# ADVERSE EVENT FOLLOWING IMMUNIZATION AND ITS MANAGEMENT IN PEDIATRIC POPULATION


A Dissertation submitted to

**The Tamil Nadu Dr. M.G.R. Medical University**

**Chennai-600 032**

In partial fulfillment of the requirements for the award of the Degree of

**MASTER OF PHARMACY**

**PHARMACY PRACTICE**

**Submitted by**

**K.RAMESH**

**261540655**

**Under the Guidance of**

**Mrs.G.Andhuvan, M.Pharm. (Ph.D.,)**

**Associate Professor**

**Department of Pharmacy Practice**


**PSG COLLEGE OF PHARMACY**

**PEELAMEDU,**

**COIMBATORE – 641004**

**MAY 2017**

# CERTIFICATE

This is to certify that the dissertation entitled **"Adverse event following immunization and its management in pediatric population"** submitted by **University Reg. No. 261540655** is a bonafide work carried out by the candidate under the guidance of **Mrs.G.Andhuvan, M Pharm.,(Ph.D).,**and submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the Degree of **Master of Pharmacy** in **Pharmacy Practice** at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2016-2017.

Place: Coimbatore
Date:

**Dr. M. RAMANATHAN, M.Pharm, Ph.D.,**
**Principal**

**Dr. PRUDENCE.A.RODRIGUES, M.Pharm,Ph.D.,**
**Head of the Department**

**Mrs. G.ANDHUVAN, M.Pharm.,(Ph.D).,**
**Associate Professor**

**Dr. M. RAMANATHAN, M.Pharm, Ph.D.,**

Principal,
PSG College of Pharmacy,
Coimbatore- 641004. (T.N)

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Place: Coimbatore **Dr. PRUDENCE.A.RODRIGUES, M.Pharm, Ph.D.,**

Date: **Head of the Department**

**Mrs. G.ANDHUVAN, M.Pharm.,(Ph.D.,)**

Associate Professor
Department of Pharmacy Practice,
PSG College of Pharmacy,
Coimbatore- 641004. (T.N)

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Place: Coimbatore **Mrs. G.ANDHUVAN, M.Pharm.,(Ph.D.,)**

Date: **Associate Professor**

# DECLARATION

I do hereby declare that the dissertation work entitled **"Adverse event following immunization and its management in pediatric population"** submitted to The Tamil Nadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment for the Degree of Masters **of Pharmacy** in **Pharmacy Practice**, was done by me under the guidance of **Mrs.G.Andhuvan., M.Pharm.,(Ph.D.,) at** the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2016-2017.

**Reg. No. 261540655**

# EVALUATION CERTIFICATE

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**Examination Centre**: PSG College of Pharmacy, Coimbatore.

**Date:**

**Internal Examiner** **External Examiner**

**Convener of Examination**

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## ABSTRACT

**Objectives**

To identify the adverse events and classify the observed event and its management Incidence of adverse event after vaccination and type of reaction for different adverse event. Some question, is there in knowledge about the immunization in parents.

**Methods**

It was a prospective, observational study that included patients of either sex, under the age of five in the pediatric wards of a tertiary care hospital. Study patients were followed throughout their outpatient department. Whenever an adverse event was detected, all the required data were collected and analyzed. Data was analyzed for incidence and after classifying the WHO guidelines.

**Results**

Of the 183 children population collected data and enrolled in the study.A total of 33 adverse events was identified from 33 children. The incidence of adverse event was 18%. Female patients experienced majority (58%) of adverse events. The drug most commonly implicated in adverse event to prescribed paracetamol syrup. Among the adverse events reported, 18% of adverse events were mild. Out of 183 parents, 77% (n=140) of parents are saying yes, vaccines are important and 18% (n=33) of parents said don't know, only 5% (n=10) of parents said it was not important.

**Conclusions**

Among the pediatric population, infants, female gender and those receiving a medication are at risk of developing adverse event. Parents are had good knowledge regarding immunization. Constant monitoring is required to address the safety issue of the pediatric population, especially in infants. So most of the infant, pediatric vaccines are safety.

# INTRODUCTION

The goal of immunization is to protect the individual and the public from vaccine preventable diseases. Although modern vaccines are safe, no vaccine is entirely without risk. Some people experience events after immunization ranging from mild side effects to life-threatening, but rare, illnesses. In some cases, these reactions are caused by the vaccine; in others, they are caused by an error in the administration of the vaccine; and in the majority of cases, there is no relationship. Whatever the cause, when an adverse event following an immunization (AEFI) upsets people to the extent that they refuse further immunizations for their children, the children are much more likely to get a vaccine-preventable disease, become seriously ill, disabled, and even die. AEFI surveillance, therefore, helps to preserve public confidence in the immunization program.

To increase immunization acceptance and improve the quality of services, the surveillance of severe AEFIs must become an integral part of immunization programs. In

Response to a request by national program managers in 1990, the Expanded Program on Immunization (EPI) Global Advisory Group (GAG) of the World Health

Organization (WHO) recommended that all immunization programs should be monitored.

AEFIs and the WHO provide assistance in doing so. This guide was prepared in response.

Each step in AEFI

• Detection and reporting

• Investigation

• Data analysis

• Corrective and other action

• Evaluation

Vaccines induce protection by eliciting active immune responses to specific antigens. There may be predictable adverse reactions (side effects): most are mild and resolve quickly. However, it is not always possible to predict individuals who might have a mild or serious reaction to a vaccine. The advice in this chapter uses the World Health Organization (WHO) classification of adverse events following immunization (AEFIs). It gives an overview of

common side effects associated with vaccines and with the management of serious adverse reactions such as anaphylaxis.

AEFIs may be true adverse reactions that are intrinsic to the vaccine, or may be caused by the way it is administered or be related to an underlying condition in the recipient. Other AEFIs may be coincidental and would have occurred regardless of vaccination. Adverse events following immunization can be local (e.g. Erythema, edema, pain) or systemic (e.g. Fever, exanthema, allergic reactions), and acute (within minutes of administration) or delayed (several hours or days after administration). Depending on the clinical relevance and severity, AEFI can be classified as physiological and nonphysiological. Physiological adverse events, reflecting natural reaction to the vaccine antigen, are common; they often include elevated body temperature, exanthema and myalgia, and usually have short duration. Since physiological reactions are believed to be natural, they are rarely reported. Non-physiological AEFI, sometimes referred to as hyper-reactions, are rare, unexpected and more severe than physiological AEFI, and they tend to occur in immunocompromised patients or patients allergic to vaccine components .

Parents should be given advice about AEFIs that they can expect and how such events should be managed. The leaflets on vaccinations provided by the Department of Health give information about AEFIs and include advice on their management. Fevers over 37.5˚C are common in children and are usually mild. Advice on the use and appropriate dose of paracetamol or ibuprofen liquid to treat a fever should be given at the time of immunization. Guidance on the treatment of feverish illness in children less than five years of age from the National Institute for Health and Clinical Excellence can be found. Local reactions are usually self-limiting and do not require treatment. If they appear to cause discomfort, then paracetamol or ibuprofen can be given. Whilst paracetamol and ibuprofen can lower the duration of fever and reduce distress, there is no evidence that they prevent febrile convulsions. It is not therefore recommended that these drugs are used routinely to prevent fever following vaccination as there is some evidence that prophylactic administration of antipyretic drugs around the time of vaccination may lower antibody responses to some vaccines.

Vaccination is one of the most cost-effective interventions to prevent major illnesses that contribute to child mortality in the country, particularly in environments where malnourished children, overcrowding, poverty and illiteracy reign. Knowledge (K), positive attitudes (A) and appropriate perceptions (P) about vaccination hence become one of the main tools to reduce the incidence of vaccine preventable diseases (VPDs) thus reducing childhood mortality and

morbidity. In our society, a large chunk of the population lives in rural areas, where mothers are illiterate and have numerous myths about vaccination; this results in children being immunized and susceptible and hence causes a serious policy concern. Evidence about the inequalities in vaccination practices exist even though childhood immunization has been an important part of maternal and child health services since the 1940s.1 In 2010 it was estimated that 1.7 million children died from vaccine preventable diseases. It was also noted that 19.3 million children had been incompletely vaccinated, leaving them susceptible to vaccine preventable disease mortality and morbidity. Approximately 50% of all under vaccinated children live in three countries, India is one of them.

The situation of under immunization is not only in the rural areas of the country, but also in urban areas as the migration of workers and the mushrooming of slums in urban areas are occurring at a rapid rate, and these are areas with unprecedented poverty, illiteracy, overcrowding and disease.4 National Family Health Survey-3 reports that only 43.5% of children in India receive all of their primary vaccines by 12 months of age.5 Main reasons identified for poor coverage includes inadequacy of community participation in routine immunization and Information Education and Communication activities.6 Negative parental perceptions of vaccination are also an important barrier to childhood vaccination. Therefore it is important to understand the variables that influence parental decisions to vaccinate their children and plan measures to overcome these barriers. A way to measure these variables, beliefs and behavior of parents is to conduct a Knowledge, Attitudes and Perceptions (KAP) study. With this outlook, this study was planned to assess the KAP of mothers with children less than five years of age about vaccination and to compare the KAP data between urban and rural setup.**Soundarya Mahalingam.*et.al.*,*(*2014)**

Immunization is the most cost-effective and highest-impact health intervention which reduces hospitalization, treatment costs and mortality. Through the combined effort of WHO and UNICEF, and governments, the Expanded Program of Immunization was launched; and the proportion of the world's children immunized against major vaccine-preventable diseases had increased from 20% in 1980 to over 80% in 1996—preventing more than 2.8M deaths in children, annually. Despite the success of EPI, many vaccine-preventable diseases have remained prevalent in developing countries (20% to 35% of all deaths in children under five). Vaccination efforts have doubled all over the world—following polio outbreaks in 18 countries since 2003, including in Nigeria and in neighboring Indonesia. **Sylvia E.Caingles,*et.al.*,(2011)**

Immunization was greatly reduced the burden of infectious diseases. Immunization prevents illness, disability and death from vaccine-preventable diseases including diphtheria, measles, pertussis, pneumonia, polio, rotavirus diarrhea, rubella and tetanus. Parents' knowledge about immunization and their attitudes towards them are likely influence uptake. Mothers' knowledge about vaccination was found to be quite low and their educational status was significantly associated with the child's coverage. Despite the fact that local and systemic reactions to vaccines are identified [9], but they were found to be one of the barriers to childhood immunization among other factors. **Yousif MA,*et.al*.,**

WHO classifies **AEFI**s according to four main categories?

- Program related
- Vaccine-induced
- Coincidental
- Unknown.

## Program-related AEFIs

These are adverse events that result from inappropriate practices in the provision of vaccination. These may include:

- Wrong dose of vaccine administered
- Vaccines used beyond expiry date
- Vaccines used at inappropriate intervals
- Inappropriate route, site or technique of administration
- Vaccine reconstituted with incorrect diluents
- Wrong amount of diluents used
- Vaccine prepared incorrectly
- mixing into inappropriate combinations
- Drugs substituted for vaccine or diluents
- Vaccine or diluents contaminated

- Vaccine or diluents stored incorrectly
- Contraindications not elicited or ignored
- reconstituted vaccine kept beyond the recommended period.

## Vaccine-induced AEFIs

These are reactions in individuals specifically caused by a particular vaccine or its component parts. These may be induced, direct effects of the vaccine or one of its components, and/or due to an underlying medical condition or an idiosyncratic response in the recipient.

Direct effects of vaccines include, for example, local reactions and fever within 48 hours of DTaP/IPV/Hib, rash and fever for seven to ten days after MMR, and parotitis three weeks after MMR.

An example of an AEFI due to an underlying medical condition is vaccine associated paralysis which very rarely followed the use of live attenuated oral polio vaccine in a child with previously unrecognized severe combined immune deficiency.

Idiosyncratic responses include idiopathic thrombocytopenic purpura (ITP) within 30 days of MMR, and anaphylaxis immediately after vaccination. When there has been a confirmed anaphylactic reaction to a previous dose of the same vaccine, then this contraindicates further vaccinations with the same vaccine or a component of that vaccine.

This category also includes medical conditions that would have occurred at some point in an individual, but are triggered earlier by the vaccination. This may include febrile seizures in a child with a family history of the same, or onset of infantile spasms (Bellman *et al.*, 1983).

## Coincidental AEFIs

These are not true adverse reactions to immunizations or vaccines, but are only linked because of the timing of their occurrence. When an AEFI is coincidental, the event would have occurred even if the individual had not been immunized. An example would be people who develop a cold with coryzal symptoms following flu vaccination. The flu vaccine does not prevent the common cold and colds are common in the winter when people are receiving the flu vaccine.

**Serious event**

An AEFI will be considered serious, if it:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity,
- Is a congenital anomaly/birth defect, or
- Requires intervention to prevent permanent impairment or damage.

**Severe event**

Severe is used to describe the intensity of a specific event (as in mild, moderate or severe); the event itself, however, may be of relatively minor medical significance (e.g. Fever is a common, relatively minor medical event, but according to its severity it can be graded as mild fever or moderate fever).

In this AEFI study there are both serious or events. this study contains only the severe events, there are no serious events. where severe events are classified into mild, moderate, and severe. This study contains only mild events like fever. There any other serious events are not presented.

Some of the vaccine induced adverse events:

.15 deaths were reported from Kerala from December 2011 –January 2013. A central team was formed (circular no T13020/11/2011-CCV dated 23rd Jan 2013)investigate the spate of serious AEFI cases (including death) from **Kerala in Dec 2012.**

The team together with the members of the Kerala State AEFI committee then reviewed the cases in detail and classified them further based on the available investigation documents including the PIR and DIR of cases. This included review of cases reported with pentavalent vaccine and 2 other vaccines namely, *Infanrix* (DTaP, acellular pertussis in the DPT andnon-Hib containing vaccine) and *Easy four*(quadrivalent vaccine DPT+Hib). The discussion with the State AEFI committee members on reported AEFI deaths was put in context with the following background.

1. *Haemophilusinfluenza*type B is one of the leading causes of acute respiratory infection,pneumonia and meningitis in India and through govt. UIP program, it is made available to all strata of society free of cost.

2. The vaccine has already been used in the private sector for more than a decade.

3. Introduction of any new vaccine in the routine program is accompanied by an increased sensitivity of AEFI surveillance and hence increased reporting. (Example of Sri Lanka, where the vaccine was stopped due to increased AEFIs being reported and then restarted in the routine immunization program when the deaths were not found to be vaccinated-related)

4. Introduction of pentavalent vaccine in the routine UIP program in Kerala too was accompanied by an awareness and capacity building activities of health workers, including structured training on AEFI reporting which also contributed to better AEFI reporting from the state.

5. Profile of AEFIs expected with DPT vaccine is similar to that expected with the pentavalent vaccine due to the DPT+Hib+Heb B combination.

6. Timely receipt of PIR (within 7 days of FIR) and DIR (within 90 days of FIR) at national level is of prime importance to aid any state AEFI investigation and enables better support to the state level from the national AEFI committee and AEFI surveillance program **Agarwal:*et.al.*,(2013)**

A girl aged 4 months 6 days received second doses of diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP), inactivated polio vaccine (IPV), ha-mophilus influenzae type b (Hib) and conjugated pneumococcal vaccines in a primary care unit in 09.05.2012 they were performed according to the routine vaccination schedule of Ministry of Health. The baby received first doses on 09.03.2012 in the same unit. Her length was 62cm., body weight 6250 gr, head circumference: 41cm, body circumference: 43cm, arm circumference 15cm and no pathological symptoms were detected by physical examination On the same day 5 hours after injection, baby came with patch like several redness on her trunk. Similar skin lesions were detected on his face, back and chest re-gions. There was no dyspnea, wheezing, fever and any other abnormal signs. She had no history of food or drug allergy or previous adverse events after vaccinations. She did not have a history of asthma, food or drug intolerance. The baby was fed only with breast milk

She was diagnosed with"Urticaria"; an immediate systemic adverse reaction due to vaccination. She was treated with intramuscular prednisolone 1 mg/kg. Her symptoms completely resolved over the next 2 hours after the injection. Then the baby was sent to the secondary care unit. The next day family was invited to the polyclinic for control. There were no signs of urticaria on physical examination and all vital signs were normal. According to both timing and specific symptoms, it is consistent with an immediate type, IgE-mediated hypersensitivity reaction. It was decided that the reaction was an adverse reaction probably caused by vaccination. Skin testing would be indicated to elucidate the cause of the reaction before the administration of future doses.

Discussion

IPV vaccine is very safe and no serious vaccine adverse reaction was reported in Turkey. Similar adverse reactions related to Hib are rare. Local reactions (Pain, redness, and swelling) are most seen reactions. One of every 20 vaccinated (Hib) children, there would be fever over 38.8 ºC. Most seen adverse reaction due to DTaB are local and serious, life threatening reactions are infrequent. Especially using purified acellular DTaB instead of DTB decreased the incidence of symptoms like fever, fatigue and vomiting. Gluten allergy has also been shown to be the cause of allergic reactions with varicella, diphtheria-tetanus-acellular pertussis (DTaP)and Japanese encephalitis vaccines compared with the first dose; the fourth dose of currently licensed diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP) has been associated with increased incidences of fever, erythema, swelling and pain at the injection site. In a small percentage of children, swelling of the entire thigh or upper arm for about four days has been reported after the fourth or fifth dose of DTaP. This self-limited reaction has been documented for multiple products from different manufacturers. After the4th or 5th booster dose or after a short injection interval (<5 to 10 years) with DTaP, local side effects (13) would be seen the local and serious systemic adverse reactions due to the vaccines were observed.

Measles carry significant morbidity and mortality, and vaccination is the most effective means of prevention. Death occurs in 1 to 3 per 1000 cases of measles in the United States, with higher mortality in individuals younger than 5 years of age and among immunocompromised children. Among infants of vaccinated women, passive immunity wanes or disappears by the age of 6 months. As part of public health preparedness, characterizing the range of adverse events among young infants is crucial for understanding the safety profile of MMR vaccine. We

focused on infants younger than 9 months of age because young infants are particularly vulnerable to wild-type infection and its complications and because adverse events following MMR combined vaccine or MMRV combined vaccine as opposed to the monovalent measles vaccine have not previously been described in this age group.

In our review of VAERS, the vast majority of adverse events were nonserious, and many reports described a medication error without any adverse event per se. Fever and injection site reactions were among the most commonly reported events, as they are after routine vaccination at the age of 12–15 months. Because of the required incubation time of vaccine-strain viruses, the relevant window for MMR or MMRV-associated fever and febrile seizure is 5–12 days after vaccination. In our review, we identified only 4 cases of fever, including 1 febrile seizure, during that window. Our findings suggest that most fevers and febrile seizures in this series were not related to MMR or MMRV administration; alternative etiologies could include concurrent illness or concomitant vaccines, but the limitations of passive surveillance do not permit us to draw any definitive conclusions. We identified a small number of VAERS reports stating that MMRV had been administered to young infants, and all these adverse events were nonserious. MMRV is not indicated in infants younger than 12 months of age.

In our analysis, 17% of adverse events met the regulatory definition of serious, which is consistent with the proportion of serious reports throughout VAERS. Nearly one-half of the serious reports were of international origin, but we believe that this high proportion relates to differential reporting requirements for manufacturers regarding US and foreign reports. We did not identify any unusual patterns of events, in particular body systems or clinical categories. A single death was attributed to SIDS. Epidemiologic analyses have not revealed a casual association between childhood immunizations and subsequent SIDS. Thrombocytopenia and transient arthralgiaare known to occur after MMR vaccination, but we did not receive any reports of these events among children younger than 9 months of age. Our review identified reports of Neurodevelopment disorders after MMR vaccination, including autism. However, epidemiologic analyses that were specifically designed to evaluate a possible relationship between vaccines and autism and other Neurodevelopment disorders strongly suggest that there is no causal link. In its review of the evidence and causality of adverse effects of vaccines, the Institute of Medicine concluded that the evidence favors rejection of a causal relationship between MMR vaccine and autism.

Strengths of VAERS include its national scope, size, timeliness, ability to detect events that were not observed during prelicensure trials and surveillance among special populations. However, passive surveillance systems like VAERS are subject to many limitations, including underreporting, incomplete information, inadequate data regarding the numbers of doses administered, and lack of direct and unbiased comparison groups. Because of these and other limitations, it is usually not possible to verify causal associations between vaccines and adverse events from spontaneous reports to VAERS. Nevertheless, VAERS data have been used to describe a range of potential vaccine adverse events and to look for unexpected patterns in demographics and clinical characteristics that might lead to hypotheses that can be tested with epidemiologic studies. If widespread vaccination of infants has implemented in response to an outbreak, independent data from the FDA's Mini-Sentinel System or other sources may provide additional information about rates of adverse events among young infants given MMR vaccine. Recent media publications about measles and MMR vaccine have incorrectly stated or implied that children younger than 1 year of age cannot receive the vaccine. **LK, Baker CJ, Kimerlin DW, *et al.,(*2015)**

In this study, we actively collected data on adverse events in a sample of pediatric GPs practices. The overall rate of AEFI after routine obligatory vaccination in children identified in our study was 209 per 100,000 vaccine doses, which is 6 times higher than the officially reported rate to the State Institute for Drug Control (an agency officially responsible for recording such events). The vast majority of AEFI were mild and local; the most common systemic AEFI was a fever; and only 16% required medical treatment.

Several limitations of this study need to be considered when interpreting these results. First, although the practitioners were selected randomly, some 30% of invited GPs did not participate in the study. However, it is unlikely that non-participating practitioners had very different AEFI rates than those who participated in the study; the non-response therefore should not affect the results.

The second potential limitation is the fact that data on AEFI are based on pediatric GP records, rather than on self-reported by the parents of children. It is likely that parents would report more adverse events than pediatricians; on the other hand, physicians are the only persons who are qualified to recognize the adverse event as a non-physiological.

The third, and related, limitation is the question of what constitutes a non-physiological AEFI. Although national and WHO criteria exist, the distinction between physiological and non-physiological adverse event is blurred, and the classification may depend on a number of factors, including GPs perceptions and the attitude of parents. The literature on AEFI rates is relatively sparse. Fritsche et al., using data from the US, the Netherlands and Australia, reported a very wide range of AEFI in these countries, between 4.8 and 83.0 per 100,000 doses of vaccines [3]. Surveillance of AEFI in Zhejiang province in China in 2008–2011 found 85 adverse events per 100,000 infants under 1 year of age. As the data in these studies were collected using different methodology in each country, they cannot be directly compared; however, they do indicate the potential under-reporting of AEFI.

The rate of AEFI in the present study (209 per 100,000 doses) was significantly higher than the rate reported to the State Institute for Drug Control (34 per100,000 doses), reflecting the difference between active surveillance used in our study and passive surveillance relying on reports to the national authority. On the other hand, the reports to the Czech State Institute for Drug Control included much higher proportion of serious AEFI than we found in our data. In our study, we included all adverse events that were available in pediatric GP records. We did not exclude any event. There were no AEFI described as pupae or GBS. In 2011, the Czech State Institute for Drug Control received a total of 817 AEFI reports, of which 51% were considered serious, compared with 3% seriousness AEFI in our study. Again, this is likely to reflect differences in data collection. In the study, we were focused on the collection of all AEFI described in GP offices.

The Vaccine Adverse Event Reporting System (VAERS), maintained by the US Centre for Disease Control and Prevention and Food and Drug Administration, reported the rate of serious AEFI in 2006–2010 as 8%; this is not too far from the root seen in our study. Non-serious AEFI are much more common; consistent with our study, local events (exanthema) were the most common symptoms reported after immunization in an analysis of the Chinese reporting system in 2009.

Training of health care providers and education of the general public may improve the reporting of vaccine safety issues and gradually reduce the mistrust regarding vaccine safety harbored by some segments of the public.. In the Czech Republic, there are no detailed guidelines how AEFI should be reported, apart from the newsletter provided by the State

Institute for Drug Control Vaccination registers, which currently exist in in 11 EU countries may be a possible solution but at present there are no plans to establish an immunization registry in the Czech Republic. Although the vast majority of AEFI identified in this study were mild. An establishment of a vaccination register, which would also collect data on AEFI, should be considered to improve the evidence on this important public health issue. The best way forward would be to have a vaccination registry with linkage available to other data at the GPs or hospitals to allow robust epidemiological studies to be done on vaccine safety signals (as WHO blueprint indicates) In addition, active surveillance of rare but serious events of interest (such as done by rapid cycle analysis in the Vaccine Safety Data link) would be useful**.**
**Jana Danova,*et.al.*,**

## Vaccinations in Infants and Children

The vaccines that are recommended for routine immunization by the Centers for Disease Control and Prevention (CDC) in all children from birth through age 6 years are discussed below. For more detailed information, including exceptions and other considerations, see the CDC's full vaccines and immunizations guidelines.

The vaccines listed below are administered via intramuscular (IM) injection unless otherwise stated. IM administration in the anterolateral thigh muscle is preferred in neonates, infants, and small children. IM administration in the deltoid muscle is preferred in young children (e.g., aged 4-6 years) who are of normal weight.

**Hepatitis B vaccine** (HepB)

- Minimum age: Birth
- 3 doses
- First dose of monovalent HepB before hospital discharge*
- Second dose with monovalent or combination vaccine at age 1 or 2 months
- Third dose at age 6-18 months
- *If mother is HBsAg-positive, also administer hepatitis B immunoglobulin (HBIG) 0.5 ml within 12 hours of birth
- *If mother's HBsAg status is also unknown, administer HBIG to infants weighing < 2 kg within 12 hours of birth; determine the mother's HBsAg status as soon as possible, and, if

the mother is HBsAg-positive, also administer HBIG in infants weighing ≥2 kg as soon as possible, but not later than age 7 days

**Rotavirus vaccine** (RV)

- Minimum age: 6 weeks
- 2 or 3 doses administered *orally*
- If Rotarix is used, administer a 2-dose series at age 2 and 4 months
- If RotaTeq is used, administer a 3-dose series at age 2, 4, and 6 months
- If any dose in the series was RotaTeq or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered

**Diphtheria, tetanus, acellular pertussis vaccine** (DTaP)

- Minimum age: 6 weeks
- Doses at ages 2 months, 4 months, 6 months, and 12-15 months
- A final dose at age 4-6 years
- If the fourth-dose DTaP vaccine was administered 4 months or more after the third dose, at an appropriate age, it can be counted as valid and need not be repeated after the recommended 6-month interval between doses 3 and 4.

**Haemophilus influenza type b vaccine** (Hib)

- Minimum age: 6 weeks
- 2- or 3-dose primary series and 1 booster dose (dose 3 or 4 depending on vaccine used for primary series) at age 12-15 months
- Doses at ages 2 months, 4 months, 6 months (brand dependent), and booster at 12-15 months

**Pneumococcal vaccine 13-valent** (PCV13)

- Minimum age: 6 weeks
- Doses at ages 2 months, 4 months, 6 months, and 12-15 months
- See the CDC's full vaccines and immunizations guidelines for updated (2015) scheduling considerations.

In 2015, the Advisory Committee on Immunization Practices provided recommendations on the pneumococcal polysaccharide vaccine (PPSV23) and the pneumococcal conjugate vaccine (PCV13), summarized as follows:

- The ACIP currently recommends that a dose of PCV13 be followed by a dose of PPSV23 in persons aged 2 years or older who are at high risk for pneumococcal disease because of underlying medical conditions.
- Children with an immune compromising condition or functional or anatomic asplenia should receive a second dose of PPSV23 5 years after the first PPSV23 dose.

**Inactivated poliovirus vaccine** (IPV)

- Minimum age: 6 weeks
- 4 doses administered IM (may administer SC or IM in depleted in older children)
- Doses at ages 2 months, 4 months, 6-18 months, and age 4-6 years

**Influenza vaccine**

- Minimum age: 6 months for trivalent inactivated vaccine(TIV) and the quadrivalent inactivated vaccine (brand dependent); 2 years for live attenuated vaccine (LAIV) (see the CDC's full vaccines and immunizations guidelines for updated [2015] LAIV contraindications/considerations)
- Children aged 6 months to 8 years who are receiving their first influenza vaccination should receive 2 doses (separated by at least 4 weeks) and then 1 dose in subsequent years

Guidelines on immunization from the American Academy of Pediatrics Committee on Infectious Diseases and the Advisory Committee on Immunization Practices specify that the live attenuated influenza vaccine (LAIV) should not be administered to some persons, including the following:

- Persons who have experienced severe allergic reactions to LAIV, any of its components, or a previous dose of any other influenza vaccine
- Children aged 2-17 years, receiving aspirin or aspirin-containing products
- Persons who are allergic to eggs

- Pregnant women
- Immunosuppressed persons
- Children aged 2-4 years with asthma or who have had wheezing in the past 12 months
- Persons who have taken influenza antiviral medications in the previous 48 hours

**Measles, mumps, and rubella vaccine** (MMR)

- Minimum age: 12 months
- Administer by *SC* into the outer aspect of the arm
- Two dose series at ages 12-15 months and 4-6 years

**Varicella virus vaccine**

- Minimum age: 12 months
- Administer by *SC* injection into the outer aspect of the upper arm or the anterolateral thigh
- Two-dose series at ages 12-15 months and 4-6 years

**Hepatitis A vaccine** (HepA)

- Minimum age: 12 months
- Two-dose series beginning at ages 12-23 months; the second dose is given 6-18 months later

The following clinical practice guidelines were released in 2015 by Help Eliminate Pain in Kids

- No aspiration should be used during intramuscular vaccine injections in individuals of all ages.
- Inject the most painful vaccine last (rather than first) during vaccine injections in individuals of all ages.
- Breast feeding should be used during vaccine injections in children aged 2 years and younger.
- Holding should be used (rather than the child lying supine) during vaccine injections in children aged 3 years and younger.
- Sitting upright should be used (rather than the individual lying supine) during vaccine injections in children aged 3 years and older and adults.

- Apply topical anesthetics before vaccine injections in children aged 12 years and younger.
- Give sucrose solution before vaccine injections in children aged 2 years and younger.
- Educate parents about pain management before the day of vaccination and on the day of vaccination.
- Educate children aged 3 years and older about pain management on the day of vaccination.
- Parents should be present during vaccine injections in children aged 10 years and younger.

## LITERATURE REVIEW

**Adriana Parrella Annette Braunack-Mayer,Michael Gold,Helen Marshall and Peter Baghurst***et.al.,* Healthcare providers' knowledge, experience and challenges of reporting adverse events following immunisation: a qualitative study described as they concluded This study provides an overview of experience and beliefs of three healthcare professional groups in relation to identifying and reporting AEFI. The qualitative assessment reveals differences in experience and awareness of AEFI reporting across the three professional groups. Most participants appreciated the importance of their role in AEFI surveillance and monitoring the ongoing safety of vaccines. Future initiatives to improve education, such as increased training to health care providers, particularly, medical professionals, are required and should be included in both undergraduate curricula and ongoing, professional development.

**F. M. Turnbull *et al*.**, describes in his **study ofthe National Study of Adverse Reactions after Vaccination with Bacille Calmette-Gue´rin in a prospective national study** Local reactions were more frequently reported by adult females than by adult males (RR, 7.18; 95% CI, 1.59–32.45). Adverse reactions were not significantly associated with any currently available vaccine batch, previous receipt of BCG vaccine, or concomitant administration of other vaccines.

**Jana Danova*et.al*.,** described the study**Active surveillance study of adverse events following immunization of children** The rate of AEFI identified in this study was considerably higher than the officially reported rate. Although the vast majority of AEFI were non-serious, health care providers and the public should be educated and encouraged to report AEFI to address the issue of underreporting, to increase the safety profile of vaccines, and to improve public confidence in immunizationprograms.

**J. Kurian,*et.al*.,** Adverse Drug Reactions in Hospitalized Pediatric Patients: A Prospective Observational Study as described the concluded asAmong the pediatric population, infants, male gender and those receiving ≥4 number of medications are at risk of developing ADRs. Constant monitoring is required to address the safety issue in pediatric population, especially in infants and patients receiving ≥4 drugs.

**Katrin S. Kohl,1 S. Michael Marcy *et.al*.,** described the study on **Fever after Immunization: Current Concepts and Improved Future Scientific Understanding** In conclusion, although many aspects of the society, medical, economic, and epidemiologic meaning of fever as an AEFI are still elusive, it is a common, generally benign, clinical sign. We consider the cost of a potentially unnecessary clinical/diagnostic evaluation of a child with fever after immunization to be clearly offset by the risk of complications of disease that would result had we no vaccination programs. In addition, a globally standardized assessment and reporting of the event, as proposed by the Brighton Collaboration, is a step toward a more rigorous scientific understanding of its incidence and true significance.

**Muchekeza M, *et al*.**, conducted **studies on Adverse Events Following Immunization (AEFI) Surveillance in Kwekwe District** Lack of knowledge of AEFI surveillance procedures was the main challenge. As a result, 150 (45%) nurses were trained in AEFI surveillance and surveillance forms were distributed to all health facilities.

**PATJA, ANNAMARI MD; *et.al*.,**described the study**Serious adverse events after measles-mumps-rubella vaccination during a fourteen-year prospective follow-up**Causality between immunization and a subsequent untoward event cannot be estimated solely on the basis of a temporal relation. Comprehensive analysis of the reported adverse reactions established that serious events causally related to MMR vaccine are rare and greatly outweighed by the risks of natural MMR diseases

**REPORT OF CENTRAL TEAM FOR ASSISTANCE IN INVESTIGATION OF SERIOUS AEFI CASES IN KERALA (4th-6th Feb 2013)** the team has concluded in the study was state officials and the field visits undertaken the team gave the following recommendations specifically for these cases and in the long term for improved AEFI surveillance in immediate and long term events.

**Salman Khazaei, *et.al*., described the study onAdverse Events Following Immunization (AEFI) in Children under 7- year of Age during 2014 in Hamedan Province, Iran** Our study shown, an increased risk of AEFI in the region and point out that the programmatic error still needs to be considered. Accordingly, the more activities need to be consolidated to reduce the adverse effect. This study assessed the different aspects of AEFI which may help policy makers to improve the immunization programs.

**Soundarya Mahalingam1** , Abhijna Soori2, Pradhum Ram2, Basavaprabhu Achappa3, Mukta Chowta4 , Deepak Madi3 2014 described the study on Knowledge, attitude and perceptions of mothers with children under five years of age about vaccination in Mangalore, India its concluded A significant number of mothers in rural areas were unaware about the vaccination and its implications. Even in the urban areas we found significant lacunae in the KAP of mothers towards childhood vaccination.

**Sylvia E.** Caingles, MD*, Joanne J. Lobo, M. D*2011 described the study onSurvey on the knowledge, attitudes and practices of parents in barangay 8A, district, Davao city regarding their children's immunization its concluded Parents still lacked knowledge with regards to their children’s vaccination. The outcome of the child being fully immunized depends on the availability and affordability of vaccine, as well as, the willingness and effort of their parents.

**W. Katherine Yih, PhD, MPH. *et.al*, conducted study Active Surveillance for Adverse Events: The Experience of the Vaccine Safety Data link Project** Care with data quality,

outcome definitions, comparison groups, and length of surveillance are required to enable detection of true safety problems while minimizing false signals. Some causes of false signals in the VSD system were preventable and have been corrected, whereas others will be unavoidable in any active surveillance system. Temple scan statistics, analyses to control for confounding, and chart review are indispensable tools in signal investigation. The VSD's experience may inform new systems for active safety surveillance. Pediatrics 2011; 127:S54–S64.

**Wagon Zhou, M.D., Ph.D.*et.al,*** conducted the study on **Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS) --- United States, 1991—2001** During 1991--2001, VAERS received 128 717 reports, whereas >1,9 billion net doses of human vaccines were distributed. The overall dose-based reporting rate for the 27 frequently reported vaccine types was 11,4 reports per 100 000 net doses distributed. The proportions of reports in the age groups <1 year, 1--6 years, 7--17 years, 18--64 years, and ≥65 years were 18,1 %, 26,7 %, 8 %, 32,6 %, and 4,9 %, respectively. In all of the adult age groups, predominance among the number of women reporting was observed, but the difference in sex was minimal among children. Overall, the most commonly reported adverse event was fever, which appeared in 25,8 % of all reports, followed by injection-site hypersensitivity (15,8 %), rash (unspecified) (11 %), injection-site edema (10,8 %), and vasodilatation (10,8 %). A total of 14, 2 % of all reports described serious adverse events, which by regulatory definition include death, life-threatening illness, hospitalization or prolongation of hospitalization, or permanent disability. Examples of the uses of VAERS data for vaccine safety surveillance are included in this report.

**YU Ye-bin, HUANG Ke *et.al.*, Analysis of surveillance data for adverse events following immunization during year 2006-2011 in Yangchun** conducted the study onduringthe year 2006-2011 AEFI incidence in Yangchun was within the reported range under the national pilot

estimation. There is a need to standardize immunization work, improve the quality of vaccination and strengthen AEFI surveillance, so as to reduce the occurrence of adverse events after vaccination and improve AEFI surveillance sensitivity.

**Yousif MA,** *et al.*,Ahmed Abdulrahman Albarraq, Mustafa Awad A Abdallah and Abubaker Ibrahim Elbur* described the study on Parents′ Knowledge and Attitudes on Childhood Immunization, Taif, Saudi Arabia and its concluded the study on Although parents had good knowledge and positive attitudes on some aspects related childhood immunization, gaps in both studied domains were identified. Educational interventions are needed to upgrade parents' knowledge with special emphasis on less educated and residents of rural areas.

## AIM AND OBJECTIVES

**AIM:**

To identify the adverse event following immunization and its management in the Pediatric Population.

**OBJECTIVES:**

**Primary objective:**

- Classify the observed adverse event and its management
- Incidence of adverse event after vaccination.
- Type of reaction for different adverse event.

**Secondary objective:**

- Knowledge about the immunization in parents.

## 5. PLAN OF STUDY

The study was planned with four different phases:

**PHASE I:**

- Preliminary literature survey

**PHASE II:**

- Obtaining approval from ethical committee
- Literature survey

**PHASE III:**

- Data collection
- Data collection form
- Data analysis

**PHASE IV:**

- Results and discussion.

## 6. METHODOLOGY

- ✓ **STUDY TYPE**

  Prospective observational study.

- ✓ **STUDYSITE**

  The study was carried out in PSG hospital, Department of Pediatrics.

- ✓ **STUDY DURATION**

  October 2016 to April 2017

- ✓ **INCLUSION CRITERIA:**

  Both male and female children are in birth to 5 years.

  Those who are willing to participate in the study

  Patients those who will be available during the study

  Children undergoing vaccination according WHO guidelines.

- ✓ **EXCLUSION CRITERIA:**

  More than 5 years

  Birth deformity children.

- ✓ **SAMPLE SIZE:**

  183 patients

- ✓ **STUDY TOOLS:**

  Patient data collection form

  Knowledge questionnaire

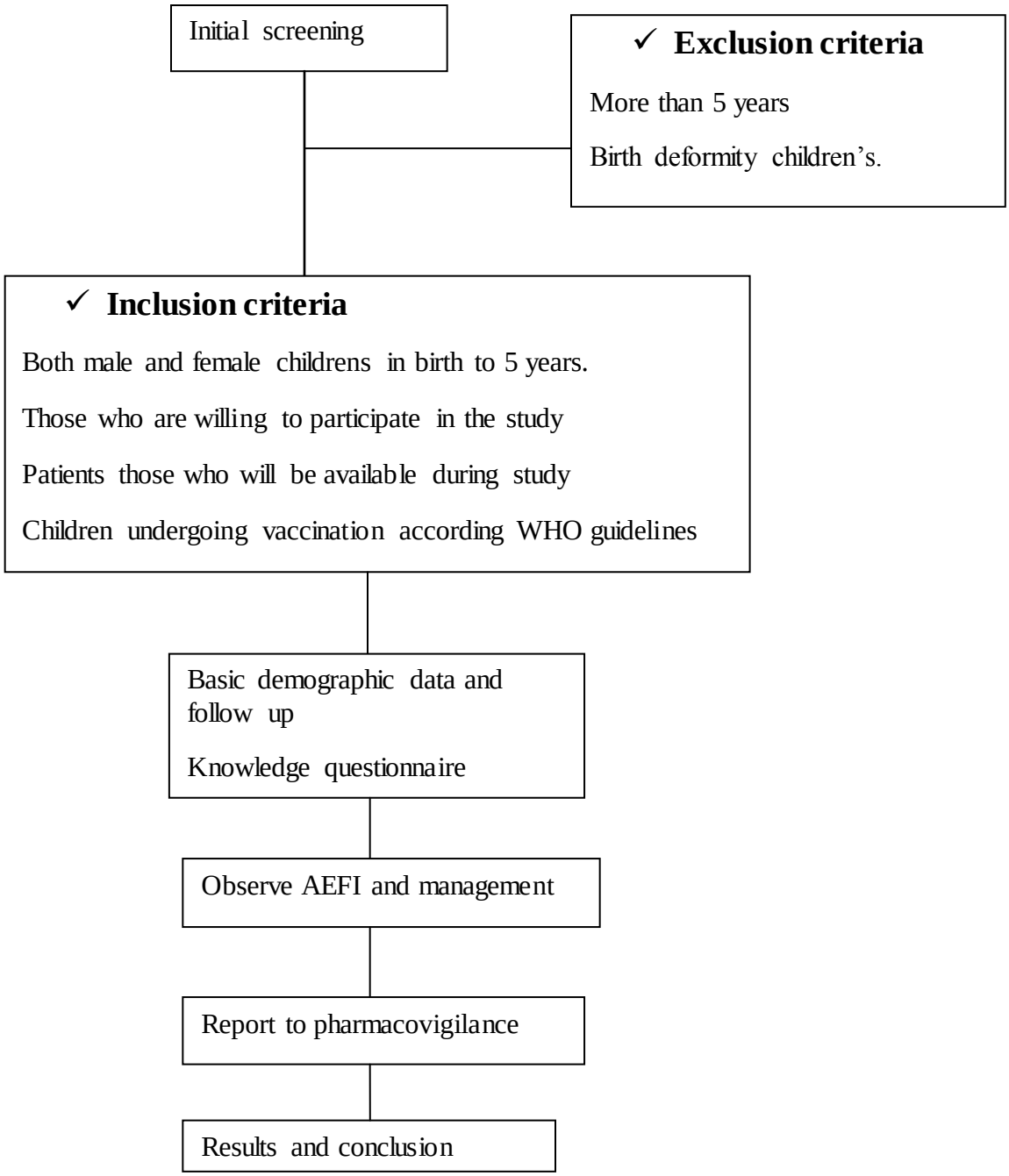
- ✓ **DATA COLLECTION:**

A prospective observational study was carried out on childrens in the Paediatrics Outpatient, Department of PSGIMS&R, COIMBATORE.

✓ **STUDY APPROVAL**:

The approval for the study was obtained from the Institutional Human Ethical Committee (IHEC), PSGIMS&R,Coimbatore**Project no: 16/336**

**METHODOLOGY:**



## RESULTS

### ACCORDING TO GENDER

Out of 183 patients, 42 % (n=76) were male children and 58 % (n=107) were female childrens as shown in Table 1 and Fig 1.

| GENDER | TOTAL | PERCENTAGE |
|---|---|---|
| Male | 76 | 42% |
| Female | 107 | 58% |
| **TOTAL** | **183** | **100%** |

**Table-1: Percentage distribution of patients, according to gender**

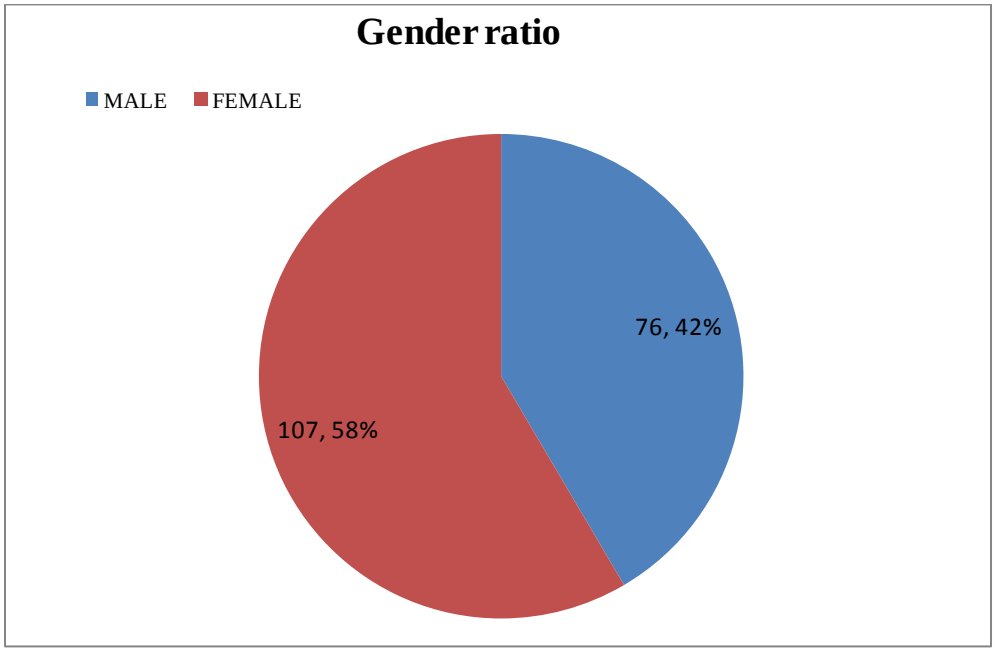



**Figure-1: Pie Chart showing the percentage distribution of patients, according to gender**

**ACCORDING TO AGE SECTOR**

Out of 183 patients, 34% (n=63) patients belong to age sector 0-6 month and 17% (n=31) of patients belongs to 6-12 month and 34% (n=62) of patients belongs to 1-3 year and 15% (n=27) of patients belongs to 3-5year as shown in Table 2 and Fig 2.

| AGE | TOTAL | PERCENTAGE |
|---|---|---|
| 0-6months | 63 | 34% |
| 6-12months | 31 | 17% |
| 1-3years | 62 | 34% |
| 3-5years | 27 | 15% |
| **TOTAL** | **183** | **100%** |

**Table-2: Percentage distribution of patients, according to age**

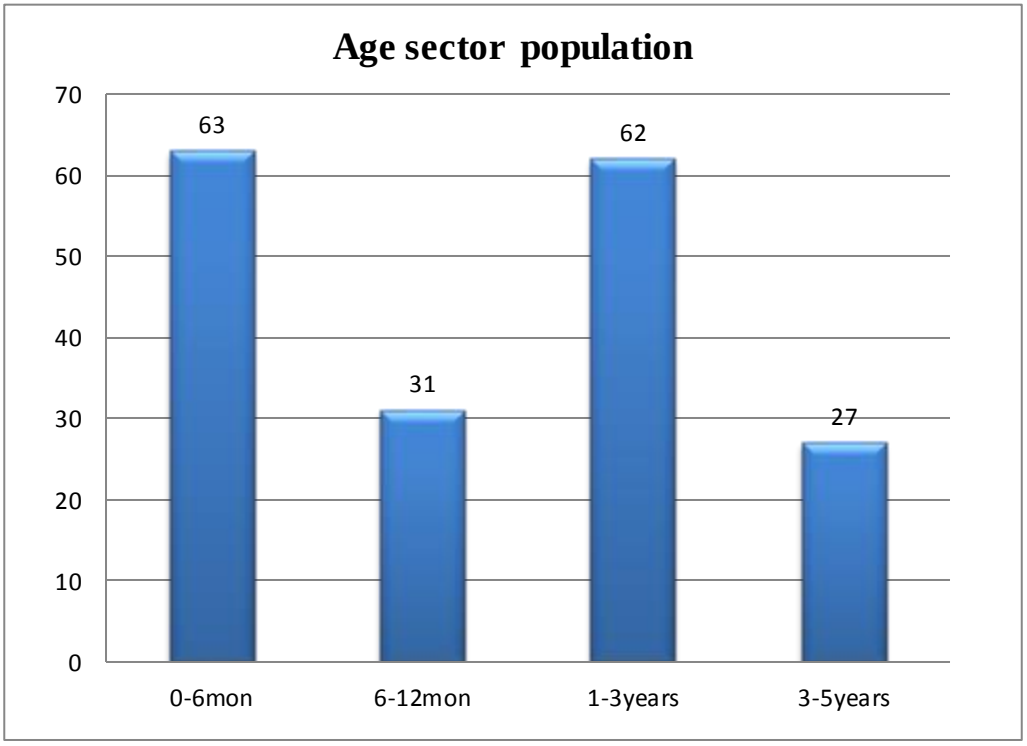



**Figure-2: Bar diagram showing the percentage distribution according to age**

**ACCORDING TO PERCENTAGE OF AEFI**

Out of 183 patients 18% (n=33) of children were developed AEFI and 60% (n=110)of the children were normal shown in Table 3 and Figure 3.

| CATEGORY | TOTAL | PERCENTAGE |
|---|---|---|
| AEFI | 33 | 18% |
| NORMAL | 110 | 60% |
| NO RESPONSE | 40 | 22% |
| **TOTAL** | **183** | **100%** |

**Table-3: Percentage distribution of patients, according to AEFI**

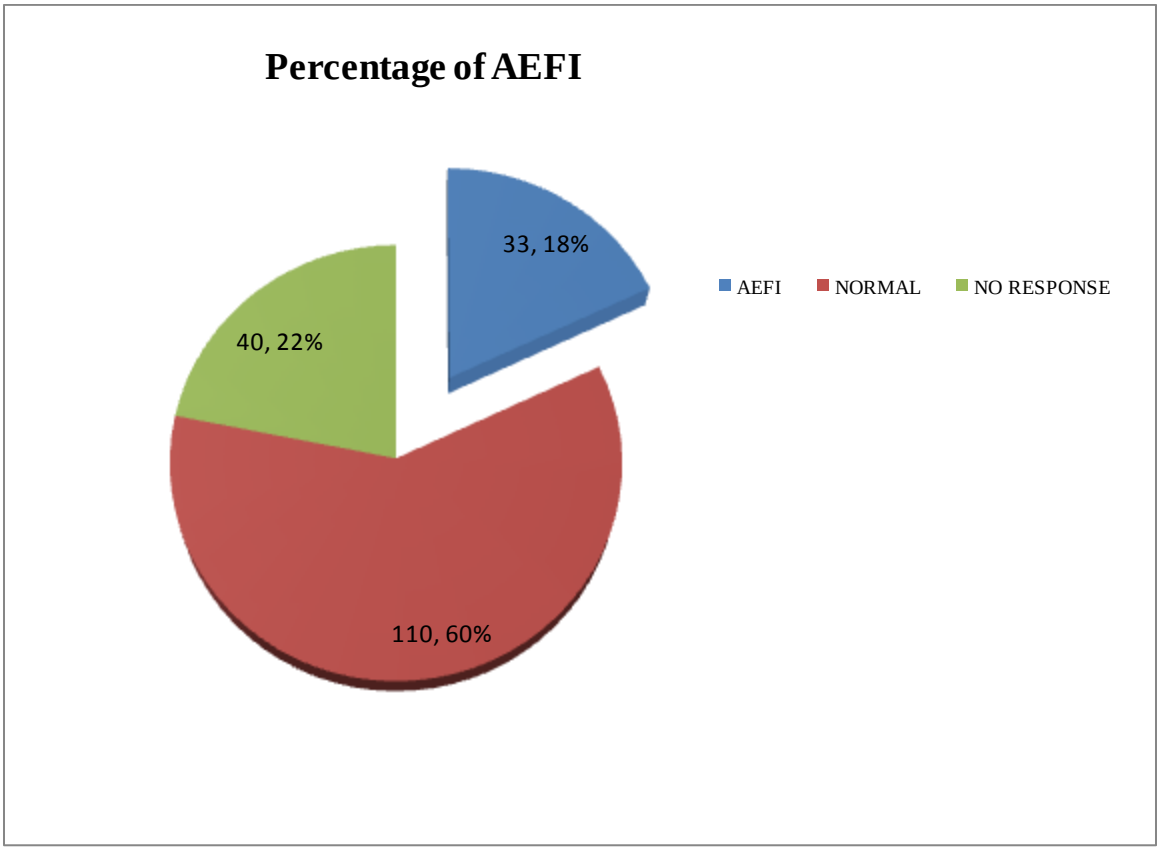



**Figure-3: Pie Chart showing the percentage distribution of patients, according to AEFI**

**ACCORDING TO MONTH WISE POPULATION**

Out of 183 patients, according to month wise population, 19% of the population were vaccinated in November month and 21% of the population were vaccinated in December month and 22% of the population were vaccinated in January month and 23% if patients were vaccinated in February month and finally 15% of patients only were vaccinated in march month shown in Table 4 and Figure 4.

| MONTH | VACCINE POPULATION | PERCENTAGE |
|---|---|---|
| NOVEMBER | 35 | 19% |
| DECEMBER | 38 | 21% |
| JANUARY | 40 | 22% |
| FEBRUARY | 42 | 23% |
| MARCH | 28 | 15% |
| **TOTAL** | **183** | **100%** |

**Table-4: Percentage distribution of patients, according to month wise vaccine Population**

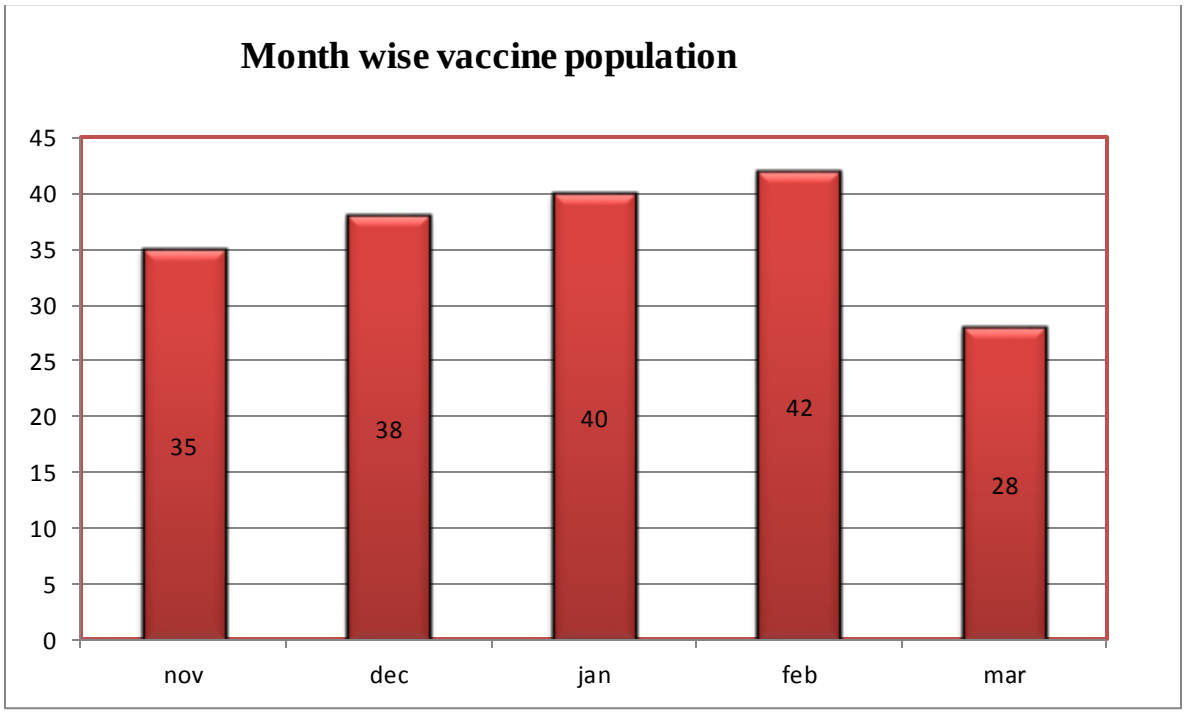



**Figure-4: Bar diagram showing the percentage distribution according to month wise vaccine Population**

**ACCORDING TO VACCINE WISE POPULATION**

Out of 183 patients 19% of the population are vaccinated Hep B is shown in Table 5 and Figure 5.

| VACCINE | POPULATION | PERCENTAGE |
|---|---|---|
| HEPATITITS B | 35 | 19% |
| POLIO | 25 | 14% |
| DTP | 28 | 15% |
| Hib type b | 22 | 12% |
| ROTAVIRUS | 12 | 7% |
| MEASLES | 03 | 2% |
| RUBELLA | 09 | 5% |
| Hepatitis A | 16 | 9% |
| MUMPS | 12 | 7% |
| VARICELLA | 18 | 10% |
| **TOTAL** | **183** | **100%** |

**Table-5: Percentage distribution of patients, according to vaccine wise population.**

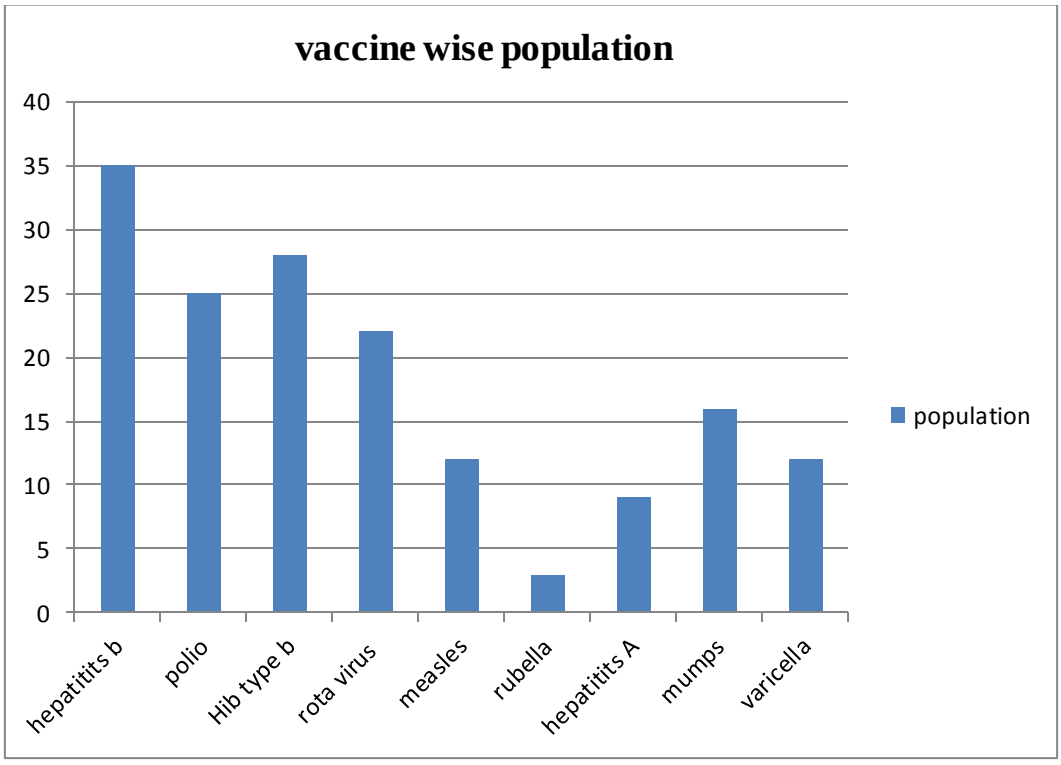



**Figure-5: Bar diagram showing the percentage distribution according to vaccine wise population**

**ACCORDING TO AEFI IN FEVER**

Out of 183 patients in the study, and the 33 patients having fever as an adverse event. The 58% (n=19) of female children having fever and 42% (n=19) of male children having fever shown in Table 6 and Figure 6

| GENDER | POPULATION (fever) | PERCENTAGE |
|---|---|---|
| MALE | 14 | 42% |
| FEMALE | 19 | 58% |
| **TOTAL** | **33** | **100%** |

**Table-6: Percentage distribution of patients, according to AEFI.**

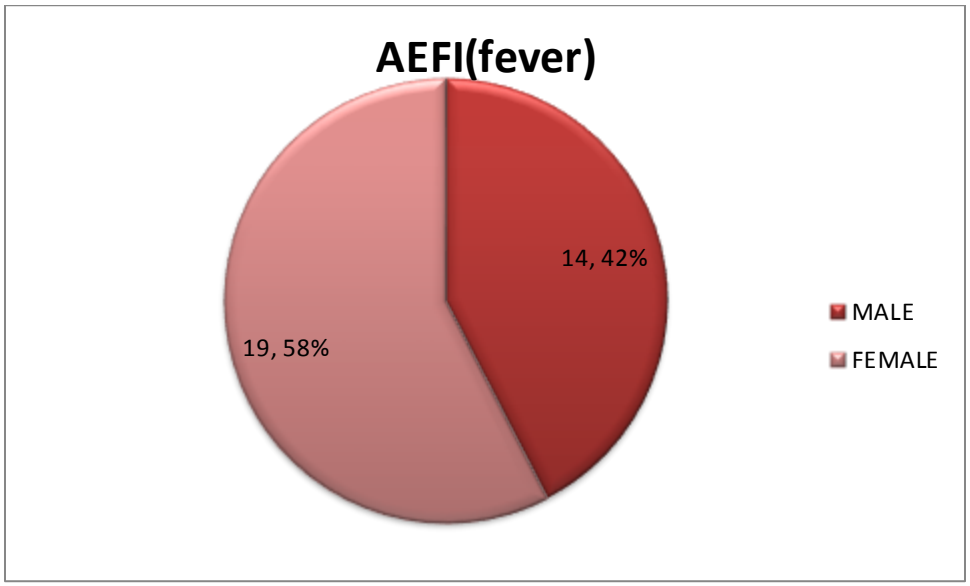



**Figure-6 Pie Chart showing the percentage distribution according to AEFI (fever)**

**RESULTS FOR KNOWLEDGE OF THE PARENTS ABOUT VACCINATION**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-1**

1. **Do you think vaccine is important?**

Out of 183 parents, 77% (n=140) of parents are saying yes, vaccines are important and 18% (n=33) of parents said don't know, only 5% (n=10) of parents said it was not important shown in Table 7 and Figure 7

| Question 1 | Population | Percentage |
|---|---|---|
| Yes | 140 | 77% |
| No | 10 | 5% |
| Don't know | 33 | 18% |
| Total | 183 | 100% |

**Table 7: Percentage distribution of population knowledge about question 1**

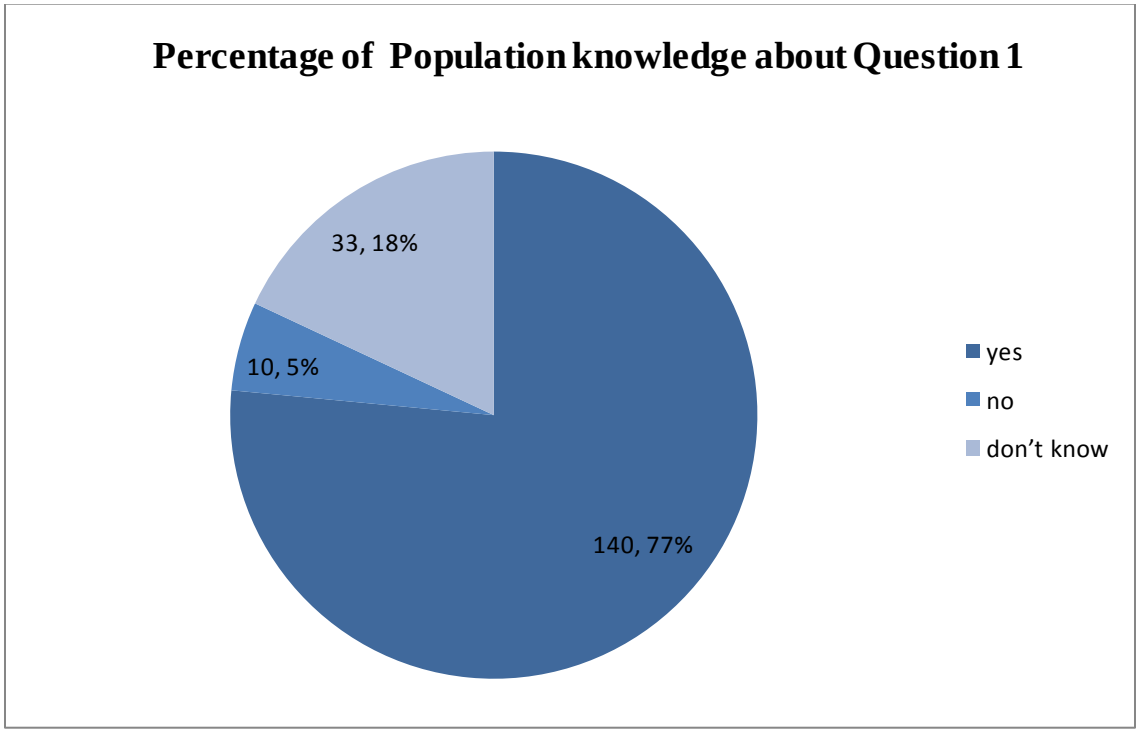



**Figure 7: Pie Chart showing the percentage distribution of population knowledge about question 1**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-2**

**Is it important to follow the vaccination schedule?**

The 67% of parent population told that the vaccination schedule was important and 15%of parents said it was not important shown in Table 8 and Figure 8.

| Question 2 | Population | Percentage |
|---|---|---|
| Yes | 123 | 67% |
| No | 27 | 15% |
| Don't know | 33 | 18% |
| Total | 183 | 100% |

**Table 8: Percentage distribution of population knowledge about question2**

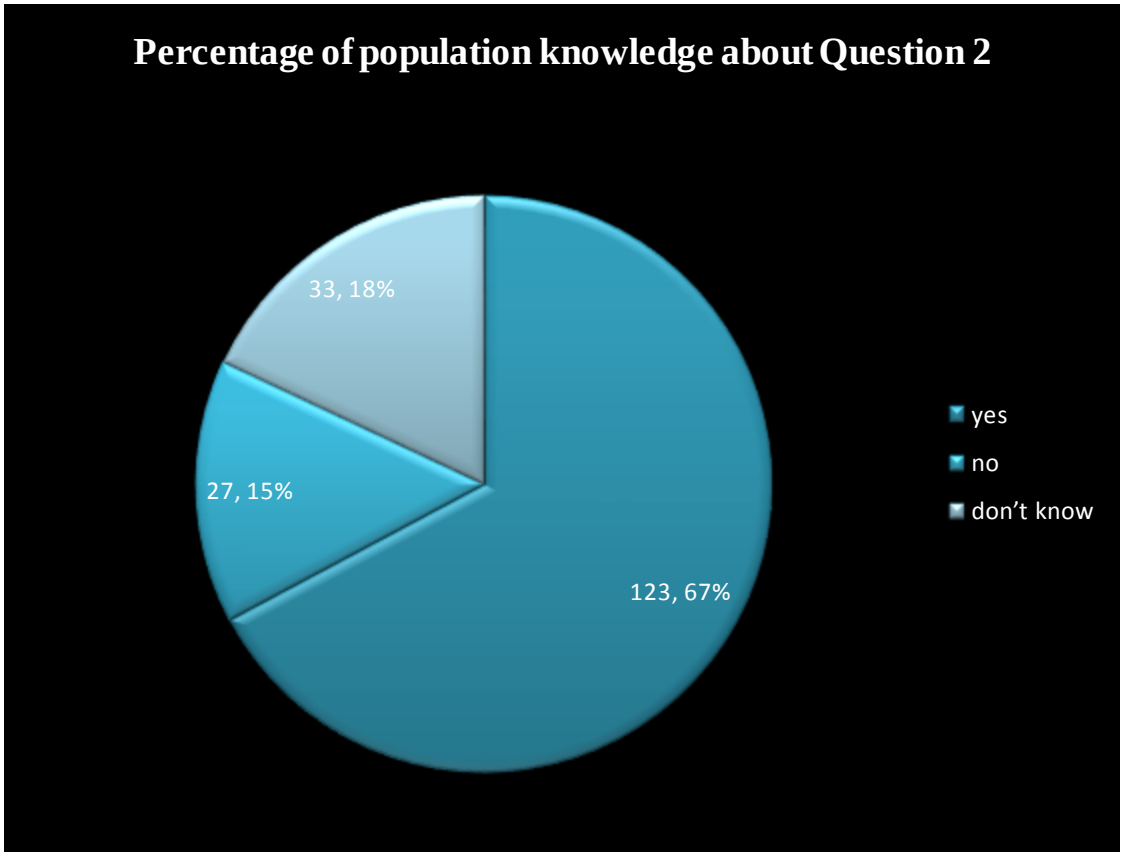



**Figure 8: Pie Chart showing the percentage distribution of population knowledge about question 8**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION**

**What is the maximum age of vaccines can be administered?**

Out of 183 parents, 53% (n=98) of parents were answered the vaccination is 5 years and 32% (n=58) of parents are saying 10 years and 15% (n=27) parents are saying adults shown in Table 9 and Figure 9.

| Question 3 | Population | Percentage |
|---|---|---|
| 5 years | 98 | 53% |
| 10 years | 58 | 32% |
| Adults | 27 | 15% |
| Total | 183 | 100% |

**Table 9: Percentage distribution of population knowledge about question3**

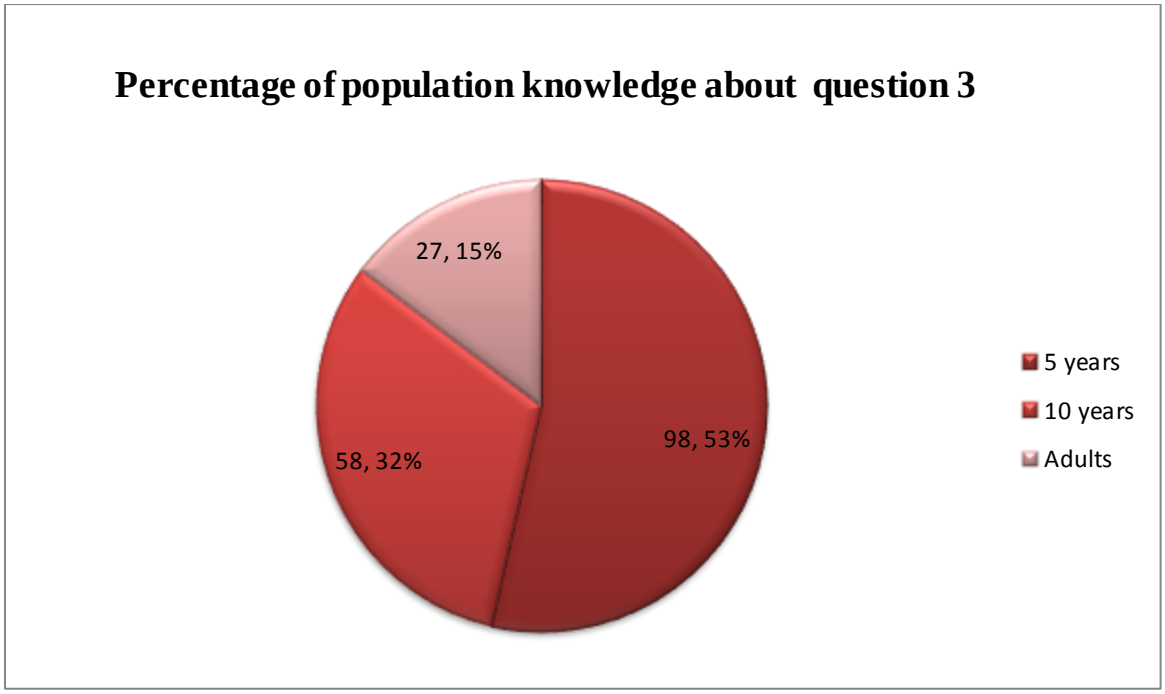



**Figure 9:Pie Chart showing the percentage distribution of population knowledge about question 3**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-4**

**Would you vaccinate with fever?**

Out of 183 parents,32 %( n=59) of parents were ready to vaccinate with fever, major parent population was not agreed to vaccinate with fever shown in Table 10 Figure 10.

| Question 4 | Population | Percentage |
|---|---|---|
| Yes | 59 | 32% |
| No | 124 | 68% |
| Total | 183 | 100% |

**Table 10: Percentage distribution of population knowledge about question4**

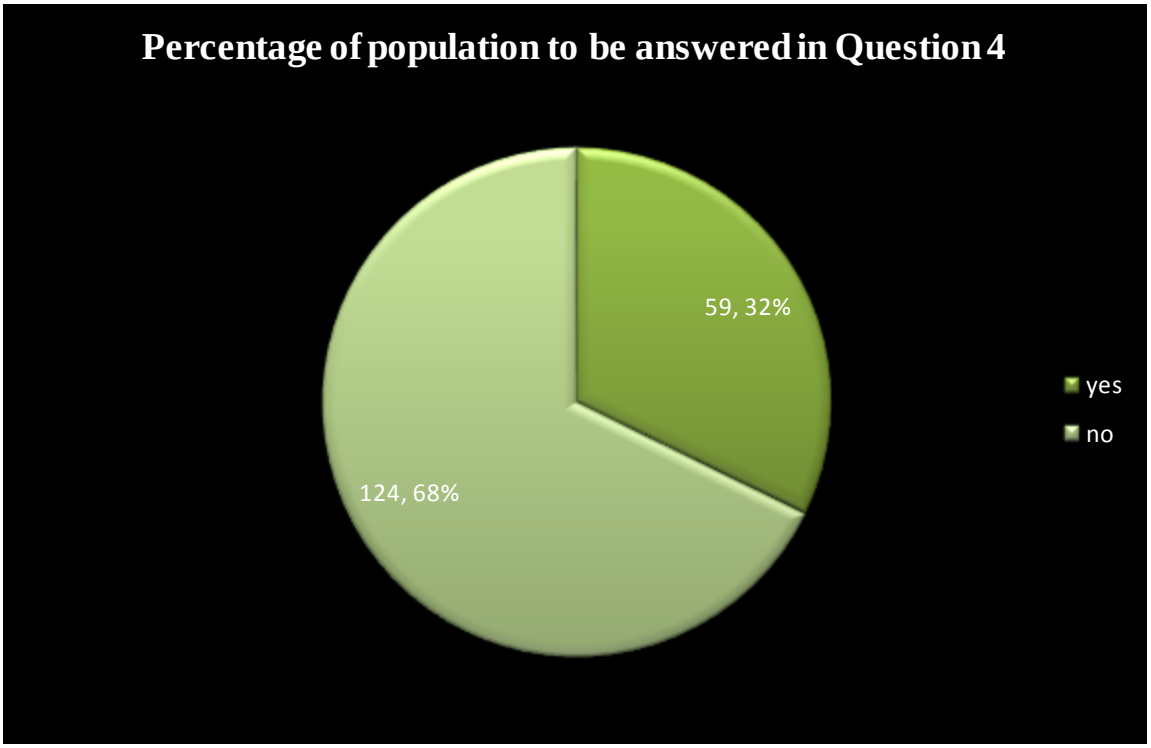



**Figure 10:Pie Chart showing the percentage distribution of population knowledge about question 4**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-5**

**Would you vaccinate in summer?**

Out of 183 parents, 46% (n=85) of parents were ready to vaccinate in summer, and 30% (n=55) of parents are not agreeing to vaccinate in summer and minor percentage of the population are said don't know shown in Table 11 and Figure 11.

| Question 5 | Population | Percentage |
|---|---|---|
| Yes | 85 | 46% |
| No | 55 | 30% |
| Don't know | 43 | 24% |
| Total | 183 | 100% |

**Table 11: Percentage distribution of population knowledge about question 5**

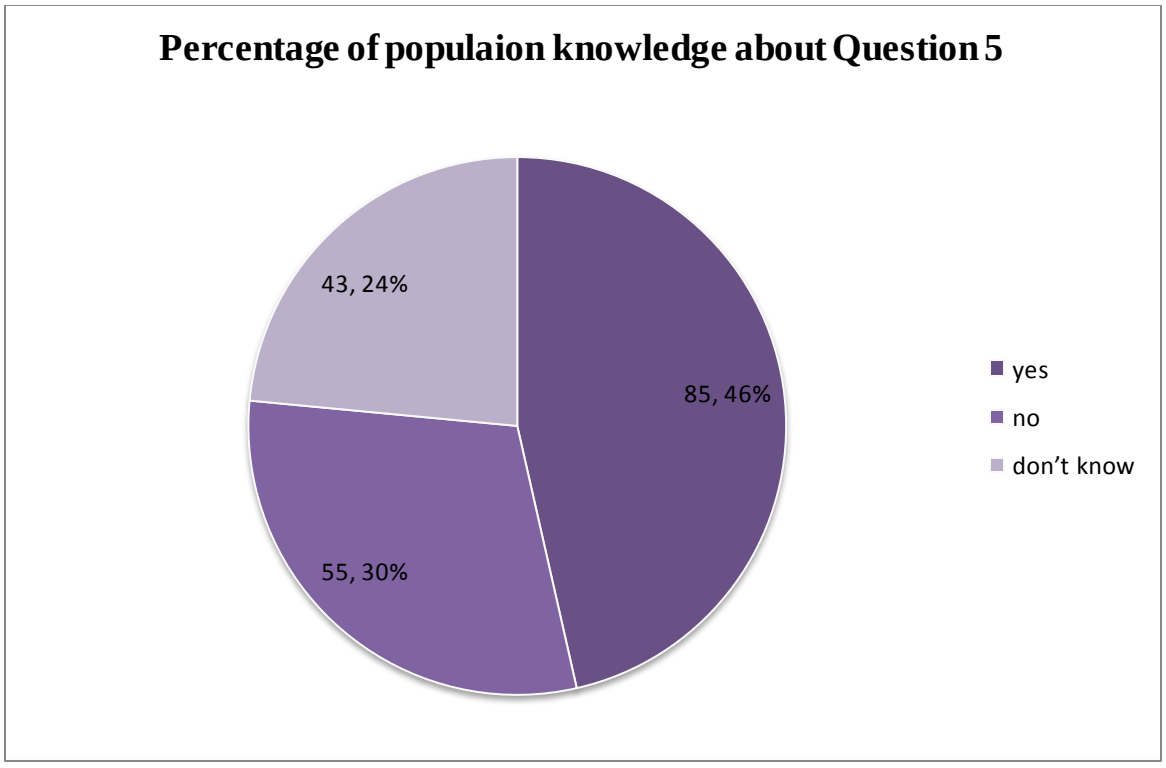



**Figure 11: Pie Chart showing the percentage distribution of population knowledge about question 5**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-6**

**Would you vaccinate with cold?**

Out of 183 parents, 22% (n=41) of parents were ready to vaccinate with cold, major parent population was not agreed to vaccinate with cold shown in Table 12 Figure 12.

| Question 6 | Population | Percentage |
|---|---|---|
| Yes | 41 | 22% |
| No | 142 | 78% |
| Total | 183 | 100% |

**Table 12: Percentage distribution of population knowledge about question6**

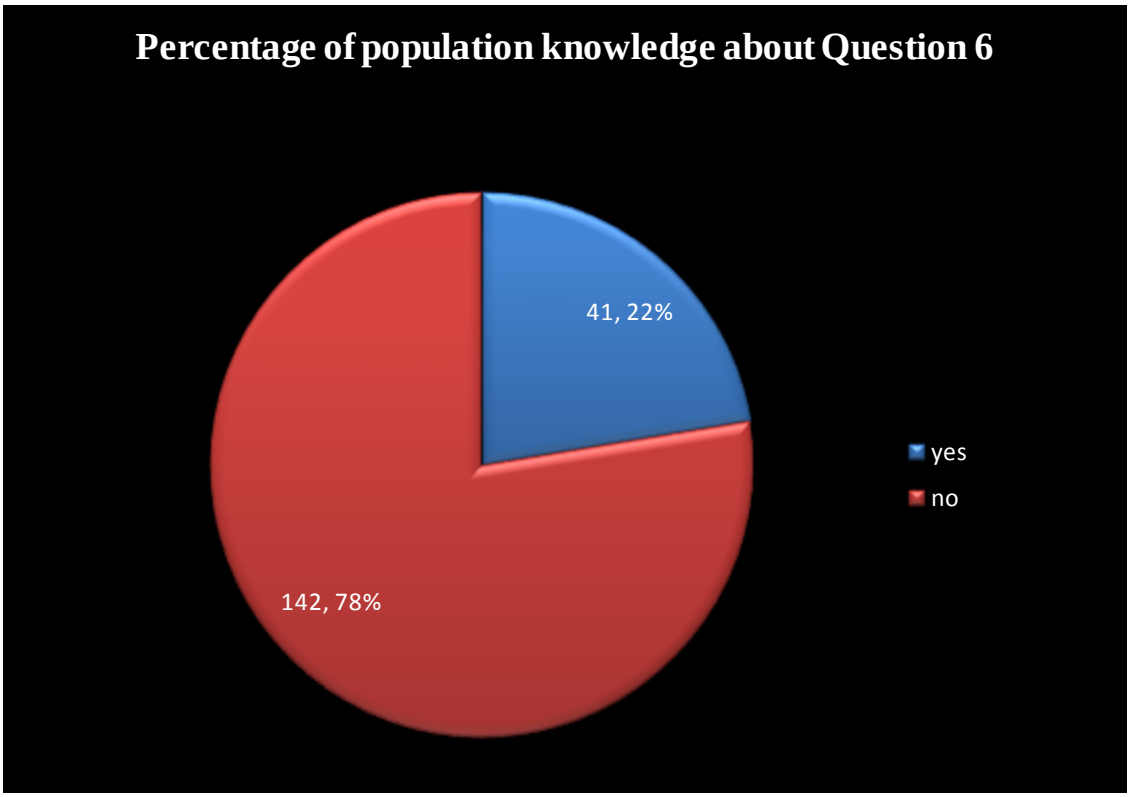



**Figure 12: Pie Chart showing the percentage distribution of population knowledge about question 6**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-7**

**Will side effect appear after vaccination?**

Out of 183 parents, 18% (n=33) of parents were told after vaccination side effect will appear and 60% (n=110) of parents were telling side effect was not appearing shown in Table 13 and Figure 13.

| Question 7 | Population | Percentage |
|---|---|---|
| Yes | 33 | 18% |
| No | 110 | 60% |
| Don't know | 40 | 22% |
| Total | 183 | 100% |

**Table 13. Percentage distribution of population knowledge about question7**

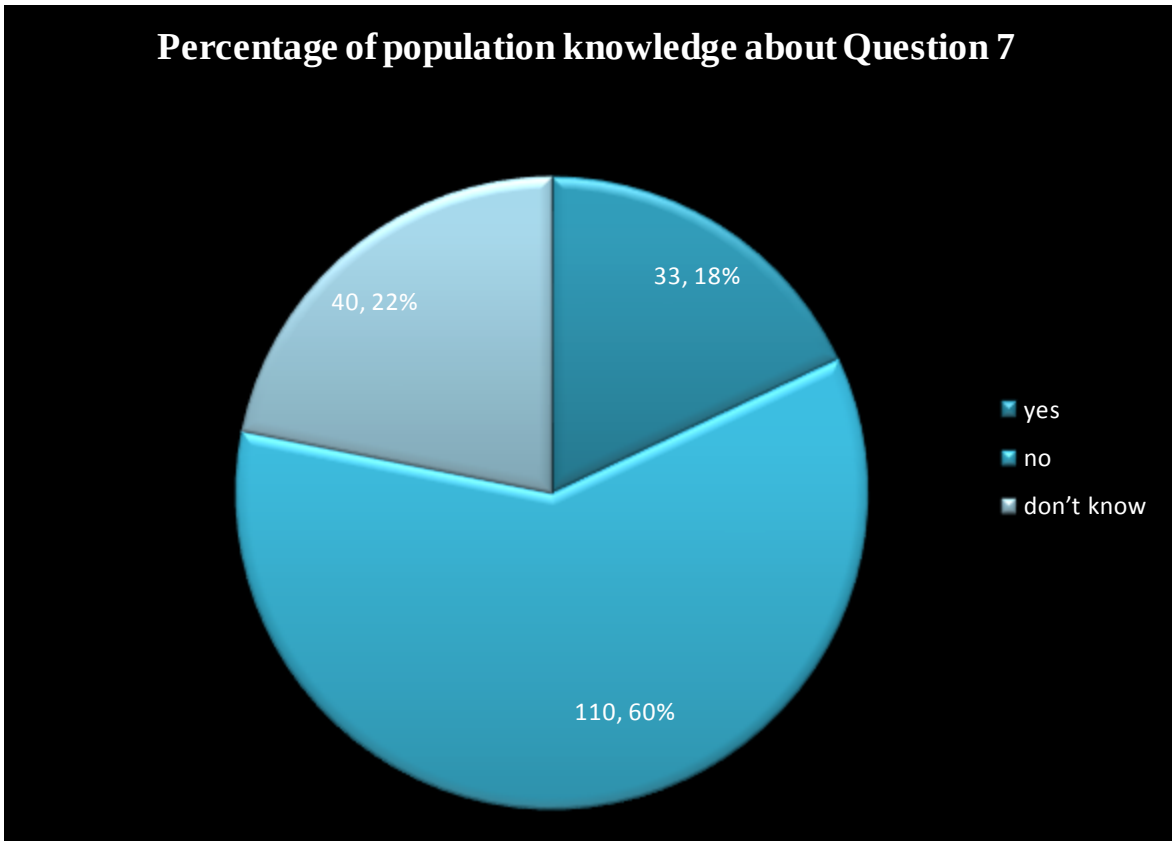



**Figure 13:Pie Chart showing the percentage distribution of population knowledge about question 7**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-8**

**Will you inform the doctor/health care worker about the side effect seen in your child?**

If they identify any side effects will inform 71%(n=130) of parents told and 13%(n=23) of parents are saying will not inform doctors or any other health care workers shown in Table 14 and Figure 14.

| Question 8 | Population | Percentage |
|---|---|---|
| Yes | 130 | 71% |
| No | 23 | 13% |
| Don't know | 30 | 16% |
| Total | 183 | 100% |

**Table 14: percentage distribution of population knowledge about question8**

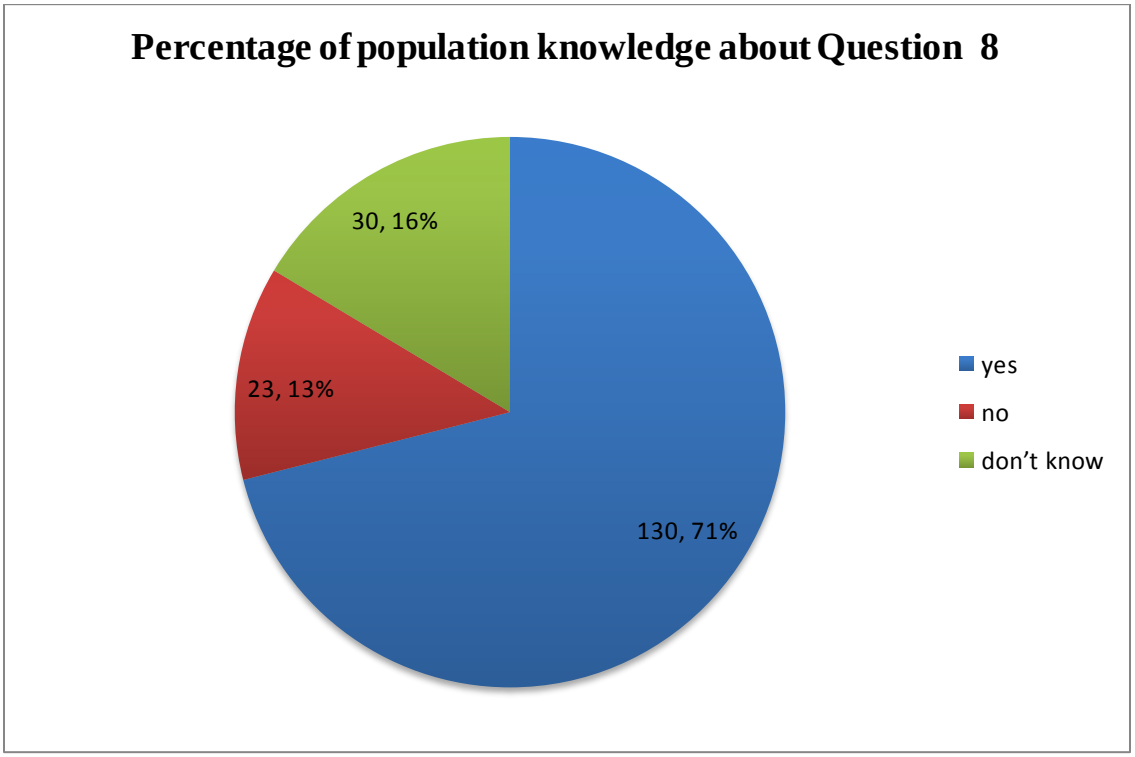



**Figure 14:Pie Chart showing the percentage distribution of population knowledge about question 8**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-9**

**Whether vaccines are harmful?**

The 17% (n=31) of parents were filled yes and 45% (n=85) of parents filled no and the 38% (n=70) of parents were filled don't known shown in Table 15 and Figure 15.

| Question 9 | Population | Percentage |
|---|---|---|
| Yes | 31 | 17% |
| No | 82 | 45% |
| Don't know | 70 | 38% |
| Total | 183 | 100% |

**Table 15: Percentage distribution of population knowledge about question9**

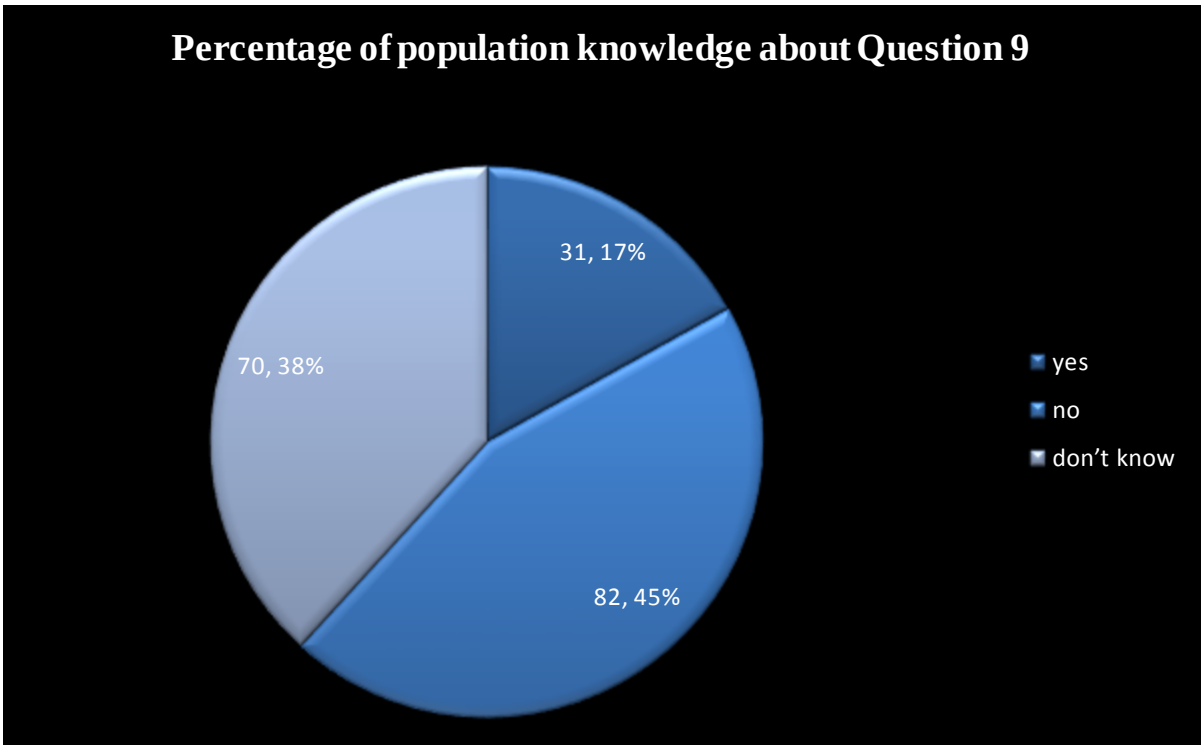



**Figure 15: Pie Chart showing the percentage distribution of population knowledge about question 9**

**PERCENTAGE OF POPULATION KNOWLEDGE ABOUT QUESTION-10**

**Till now whether immunization was completed as per the WHO schedule for your children?**

The 73% (n=133) of parents were going as per the WHO immunization schedule and 27% (n=50) of parents were represented they don't know about schedule vaccination shown in Table 16 and Figure 16.

| Question 10 | Population | Percentage |
|---|---|---|
| Yes | 133 | 73% |
| No | 50 | 27% |
| Total | 183 | 100% |

**Table 16:Percentage distribution of population knowledge about question 16**

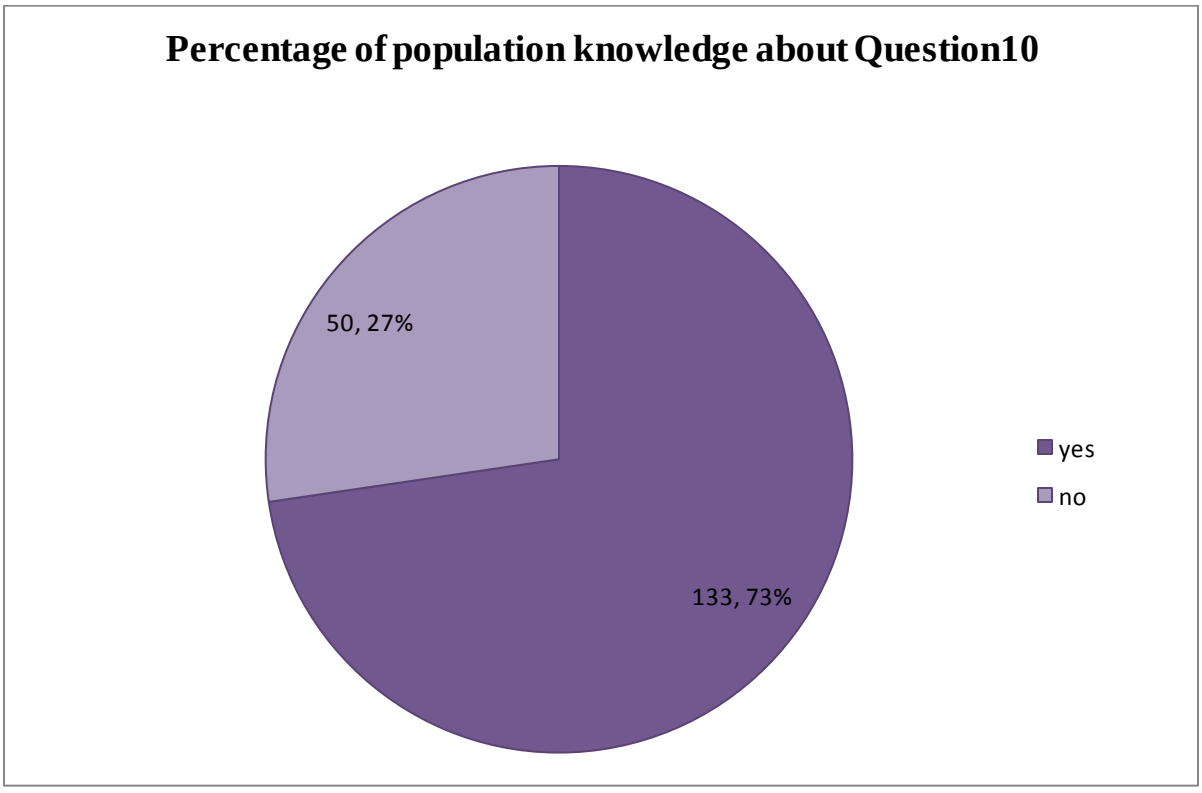



**Figure 16:Pie Chart showing the percentage distribution of population knowledge about question 10**

Answered for the question **where did you look the immunization vaccines:**

Out of 183 parents are 18% (n=33) of parents are looking in the internet and 25% (n=45) of parents are looking in clinics and 15% (n=28) of parents are looking in media and 25% (n=45) of parents are looking in a magazines and 17% (n=32) of parents are asking neighbors shown in table 11 and figure 11.

| | Population | Percentage |
|---|---|---|
| Internet | 33 | 18% |
| Clinics | 45 | 25% |
| Media | 28 | 15% |
| Magazine | 45 | 25% |
| Neighbours | 32 | 17% |
| Total | 183 | 100% |

**Table 17: Percentage distribution of population where did you look the immunization vaccines**

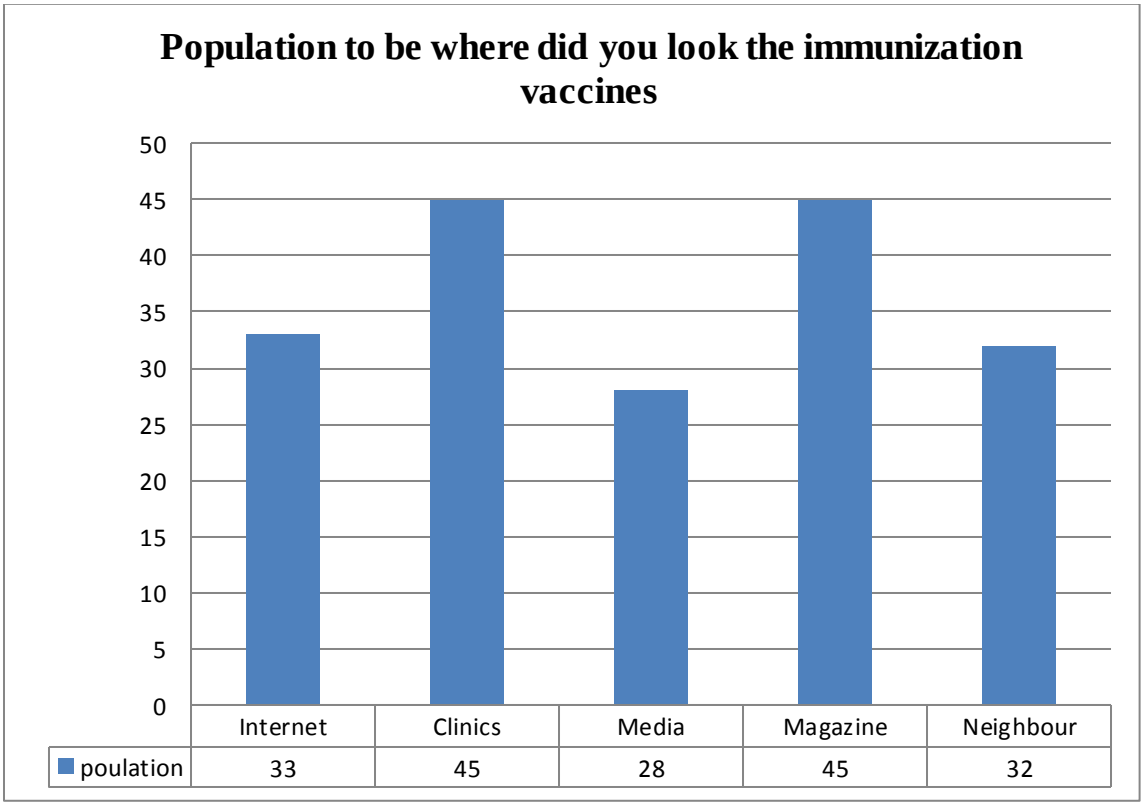



**Figure-17: Bar diagram showing the percentage distribution of population where did you look the immunization vaccines?**

# DISCUSSION

In this study, we actively collected data on adverse events in a sample of pediatric GPs practices. The majority of the AEFI cases were either mild or moderate in severity. Common reported reactions include fever. Identification of AEFI enables the improvement of health care routines for children and contributes to interventions aiming at the safety of vaccines as the passive surveillance of AEFI may be considered useful in the monitoring of vaccine-related safety.

A potential limitation is that fact the data on AEFI are based on pediatric GP records, rather than Oneself-reported by the parents of children. It is likely that parents would report more adverse Events than pediatricians on the other hand, physicians are the only persons who are qualified to recognize the adverse event as a non-physiological.

Studies have been done in different parts of the world on ADRs among pediatric patients. It has been found that ADRs were associated with 209 reported deaths among young children each year, in the age groups of newborn to 2 years of age. Similarly, in our present study, nearly 60% of the ADRs occurred in patients less than 1 year of age. A case of death had also been reported during the 2 month study period.**Danova et al. BMC Public Health (2017) 17:167**

Specific measures to prevent AEFI, including proper screening to verify possible contraindications or the need to postpone vaccines, continuous training for vaccinations, and education in health may contribute to the quality and safety of immunization, thus ensuring the advances verified in the eradication and control of diseases preventable by immunization. It is important to mention that the evidence on the safety and effectiveness of vaccines in the routine of immunization in children and adults are significantly favorable.

Here in this study Out of 183 patients, 42 % (n=76) were male and 58 % (n=107) were female, were female patients are showing a high prevalence compared to male. This shows that the female were being born more than the male child. This differed with most studies and could be explained by the distribution variation

According to age sector among the 183 children,0-6 month is a high percentage (34%) of birth

and according to percentage of AEFIamongst the patients who underwent the study, 18% had an AEFI which showed up as fever, 60% were normal and 22% of the patients did not response attending the phone call during followup.

According to vaccine wise population, the most common vaccination undertaken in this study was Hepatitis B which had 19% undertake. DTP, Polio and Hib also had a high prevalence in this study. Treatment guidelines have also shown that the main four vaccines children received are:

A. Hep B- protects against hepatitis B (infection of the liver). HepB is given in three shots. The first shot is given at the time of birth. Most states require HepB vaccination for a child to enter school.

B. RV protects against rotavirus, a major cause of diarrhea. The RV is given in two or three doses, depending on the vaccine used.

C. DTaP protects against diphtheria, tetanus, and pertussis (whooping cough). It requires five doses during infancy and childhood. DTaP boosters are then given during adolescence and adulthood.

D. Hib protects against Haemophilusinfluenzae type b. This infection used to be a leading cause of bacterial meningitis. Hib vaccination is given in four doses.

The common AEFIS include mild, moderate or severe fever, local erythema, irritability, drowsiness, rash, cough , nausea and vomiting and diarrhea among others.

Discussion on Knowledge questionnaire's which was conducted among the parents,

Analysis of the demographic characteristics of the parents participated in the present study showed that the mothers constituted the majority of the sample. Understanding the mothers' knowledge and attitudes towards immunization is important, although the father's involvement was shown to be associated with the child's vaccinationstatus. **Yousif et al., J Vaccines Vaccine (2013, 5:1).** More than half of the parents had higher education. This may be explained by the fact that the majority of the participants were living in the town where they were originally born and had better chances to complete their higher education. Assessment of the parents' knowledge in the current study showed variations in responses to questions designed

to assess their knowledge on childhood immunization. The majority of them knew that routine vaccination prevents children from some serious infectious diseases and its complication. A study conducted in UAE more than 85% of the participants knew the role of childhood vaccination in prevention of life-threatening diseases.

Current recommendation in USA is to vaccinate all children from6 months up to 19 years – with particular emphasis on children under the age of 5 year or with chronic illnesses with Influenza vaccines. According to our results 70% of parents are well knowledged.

In this study the majority of parent population had fair knowledge regarding vaccination. still some lacunae was observed in the remaining study population. This lacunae should be addressed by the health care professionals during the immunization visit.

In present study physician clinic and magazine are a main source of information regarding immunization accounting to 25% followed by internet.

The parent population reported that during fever they won't administered vaccination at cold.Thesemust be abolished and mothers must be assured regarding the safety of vaccines. 60% of study population not addressing the side effects in their children following vaccination.

Still the parents concern with the children they are ready to inform if any of the side effects seen in their children. Mothers were more aware and showed favorable attitude regarding side effects.

The study found that 73% of parent were the vaccination coverage, 27% of parent were missed one (or) two vaccination. Hence steps to be taken to ensure good education about vaccination coverage and the goals of eradication of disease like polio may be achieved.

## CONCLUSION

According to our study, 60% of patients are not affected by any adverse effect and only 18% of patients having the adverse event. The majority of adverse events are in female children. In the view of AEFI, immunization process was very perfect and does not produce any problems, so based on our study pediatric vaccines are very safety for children under the age of five years.

This study has been concluded that 70% of parents are well knowledge about immunization vaccines and some of the parents are only unknown.

Health care workers and other professionals are spontaneous to report the AEFI report to improve the reducing side effects in there serious death also.

This study demonstrates that the people should concern about risks and knowledge about immunization, all healthcare providers and the general public should be educated about AEFI report. Health care providers should be encouraged to report AEFI report to address the issue, to increase the safety profile of vaccines, and to improve public confidence in immunization programs.

Vaccine awareness should be enhanced through the use of mass media like television, radio and newspaper, as these were observed to be underutilized in this study. Government must include these newer vaccines in the national immunization program in a phase wise manner.

# BIBLIOGRAPHY


1. Active surveillance study of adverse events following immunization of children, Jana Danova, Aneta Kocourkova and Alexander M. Cello
2. Asiimwe D, Kibombo R, Matsiko J (2006) Vaccine Safety Perceptions among Parents in Developing Countries and Influence of Adverse Events Following Immunisations on their Decision to Vaccinate Children.
3. Bakhache P, Rodrigo C, Davie S, Ahuja A, Sudovar B, Crudup T et al. Health care providers' and parents' attitudes toward administration of new infant vaccines - a multinational survey. EUR J Pediatr.2013; 172 (4): 485-92.
4. Bellman MH, Ross EM and Miller DL (1983) infantile spasms and pertussis immunization.
5. Borràs E, Domínguez A, Fuentes M, Batalla J, Cardeñosa N, et al. (2009) Parental knowledge of pediatric vaccination. BMC Public Health 9: 154.
6. Burwen, D.R., Ball, R., Bryan, W., et al. (2010): Evaluation of Guillain-Barreá syndrome among recipients of influenza vaccine in 2000 and 2001. Am. J. Prev. MED., 39, 296–304.
7. Centers for Disease, Control and Prevention (2009): Safety of influenza A (H1N1) 2009 monovalent vaccines—United States, October 1–November 24, 2009. Morb. Mortal. Wkly. Rep., 58, 1351–1356.
8. Cheong, H.J., Song, J.Y., Heo, J.Y., et al. (2011): Immunogenicity and safety of influenza A (H1N1) 2009 monovalent inactivated split vaccine in Korea. Vaccine, 29, 523–527.
9. Choe, Y.J., Cho, H., Bae, G.R., et al. (2011): Guillain-Barreá syndrome following receipt of influenza A (H1N1) 2009 monovalent vaccine in Korea with an emphasis on Brighton Collaboration case definition. Vaccine, 29, 2066–2070.
10. Clothier HJ, Crawford NW, Kempe A, Buttery JP (2011) Surveillance of adverse events following immunization: the model of SAEFVIC, Victoria. Commun Dis Intell Q Rep 35: 294-298.
11. Collet, J.-P., MacDonald, N., Cashman, N., et al. (2000): Monitoring signals for vaccine safety the assessment of individual adverse event reports by an expert advisory committee. Bull. World Health Organ., 78, 178–185.

12. Coniglio MA, Platania M, Privitera D, Giammanco G, Pignato S. Parents' attitudes and behaviors towards recommending vaccinations in Sicily, Italy. BMC Public Health. 2011;11:305.
13. Dembedza E, Mudyiradima RF, Ndlovu N, Shambira G (2008) An Assessment of the Adverse Events Following Immunization Surveillance system in Zaka District, Masvingo Province
14. Deoki N, Hamid J, Utsuk D, Sumil B, Renu Pa, et al. (2009) Performance Assessment of Health Worker training in Routine Immunization in India, 2009. WHO and NIHFW collaborative study.
15. Department of Health (2001) Current Vaccine and Immunization Issues, 8 March. PL/ CMO/2001/1, PL/CNO/2001/1, PL/CPHO/2001/1.
16. En/index.html,lancet 7: 1031–4.
17. European Medicines Agency http://www.emea.europa.eu/docs/en_GB/document_library/ Scientific_guideline /2009/09/WC500003904.pdf
18. Folkenberg, M., Callreá us, T., Svanstroä m, H., et al. (2011): Spontaneous reporting of adverse events following immunization against pandemic influenza in Denmark November 2009-March 2010. Vaccine, 29, 1180–1184.
19. Greenberg, M.E., Lai, M.H., Hartel, G.F., et al. (2009): Response to a monovalent 2009 influenza A (H1N1) vaccine. N.Engl. J. MED., 361, 2405–2413.38. Clark, T.W., Pareek, M., Hoschler, K., et al. (2009): Trial of 2009 influenza A (H1N1) monovalent MF59-adjuvanted vaccine. N. Engl. J. MED., 361, 2424–2435.
20. Haber, P., DeStefano, F., Angulo, F.J., et al. (2004): Guillain- Barreá syndrome following influenza vaccination. JAMA, 292, 2478–2481.
21. Heininger U. An internet based survey on parental attitudes towards immunization. Vaccine 2006; 24(37-39):6351-6355.
22. Kapoor R and Vyas S. Awareness and Knowledge of mothers of under five children regarding immunization in Ahmedabad. Healthline, 2010;1(1):12-15.
23. Lasky, T., Terracciano, G.J., Magder, L., et al. (1998): The Guillain- Barreá syndrome and the 1992–1993 and 1993–1994 influenza vaccines. N. Engl. J. MED., 339, 1797–1802.

24. McLean American Academy of Pediatrics Committee on Infectious Diseases. Measles. In: Pickering LK, Baker CJ, Kimerlin DW, et al, Eds. *Red Book 2015 Report of the Committee on Infectious Diseases*. Elk Grove Village, IL: American Academy of Pediatrics; 2015: pp. 535–547.
25. McLean HQ, Fiebelkorn AP, Temte JL, et al; Centers for Disease Control and Prevention. Prevention of measles, rubella, congenital rubella syndrome, and mumps, 2013: summary recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep*. 2013; 62(RR-04):1–34
26. Medicines Control Agency (2000) Safety of meningococcal group C conjugate vaccines. Current Problems in Pharmacovigilance. 26, September: 14.
27. Miller M1, Turner N (2002) Suggestions for improving the monitoring of adverse events following immunization in New Zealand. N Z MED J 115: U186.
28. Ministry of Health and Child Welfare (2005) Zimbabwe Expanded Program on Immunization, Policy Document.
29. Ministry of Health and Family Welfare (2004) Guidelines for Reporting and Management of Adverse Events Following Immunizations.
30. Mollema L, Wijers N, Hahné SJ, van der Klis FR, Boshuizen HC, et al. (2012) Participation in and attitude towards the national immunization program in the Netherlands: data from population-based questionnaires. BMC Public Health12: 57.
31. Nnenna TB, Davidson UN, Babatunde OI (2013) Mothers' Knowledge and Perception of Adverse Events Following Immunization in Enugu, South-East,Nigeria. J Vaccines, Vaccine 4: 202.
32. Oh, C., Lee, J., Kang, J., et al. (2010): Safety and immunogenicity of an inactivated split-virus influenza A/H1N1 vaccine in healthy children from 6 months to º18 years of age: a prospective, open-label, multi-center trial. Vaccine, 28, 5857–5863.
33. Pfute (2006) an evaluation of the Adverse Events Following Immunizations Surveillance System in Matabeleland North Province, Zimbabwe.
34. Prymula R, Siegrist CA, Chlibek R, et al. (2009) Effect of prophylactic paracetamol administration at time of vaccination on febrile reactions and antibody responses in children: two open-labels, randomized controlled trials. Lancet 374: 1339-50.
35. Report of central team for assistance in investigation of serious AEFI cases in Kerala (4th-6th Feb 2013)Dr MK Agarwal: DC Immunization, GoI Dr NK Arora: Chairman, National AEFI Committee,. Dr Sujeet Jain.

36. Resuscitation Council UK (2008) Emergency treatment of anaphylactic reactions. Guidelines for health care providers. www.resus.org.uk/pages/reaction.pdf. Accessed: Feb 2009.
37. Simons FE, Roberts JR, GU X, Simons KJ (1998) Epinephrine absorption in children with a history of anaphylaxis. J Allergy Clin Immuno 101: 33–7.
38. Singh M L, Badole CM and Singh MP. Immunization coverage and knowledge and practice of mother regarding immunization in rural areas. Indian J Public Health 1994;38(3):103-107.
39. The UK Committee on Safety of Medicines http://www.mhra.gov.uk/thiomersal
40. United States Institute of Medicine http://www.iom.edu/Reports/2004/Immunization-Safety-Review-Vaccines-and-Autism.aspx
41. Vaccine induced adverse reaction: case reportGüzin Zeren Öztürk et.al.,
42. Varricchio, F., Iskander, J., Destefano, F., et al. (2004): Understanding vaccine safety information from the Vaccine Adverse Event Reporting System. Pediatr. Infect. Dis. J., 23, 287–294.
43. Vellozzi, C., Broder, K.R., Haber, P., et al. (2010): Adverse events following influenza A (H1N1) 2009 monovalent vaccines reported to the Vaccine Adverse Event Reporting System, United States, October 1, 2009–January 31, 2010. Vaccine, 28, 7248–7255.
44. Vellozzi, C., Burwen, D.R., Dobardzic, and A., et al. (2009): Safety of trivalent inactivated influenza vaccines in adults: background for pandemic influenza vaccine safety monitoring. Vaccine, 27, 2114–2120.
45. WHO (1997) Surveillance of Adverse Events Following Immunization: Field Guide for Managers of Immunization Programs.
46. WHO (1999) Immunization Safety Surveillance: Guidelines for Managers of Immunization Programs on Reporting and Investigating Adverse Events Following Immunization.
47. WHO (2007) Global Framework for Immunization Monitoring and Surveillance.
48. WHO (2010) Adverse Events Following Immunizations in a Changing Immunization Environment.
49. WHO (2013) Immunization safety surveillance: guidelines for Immunization program managers on surveillance of adverse events following immunization.

50. WHO (2014) Polio vaccines: WHO position paper, January 2014 - Recommendations. Vaccine.
51. World Health Organization (2009): Strategic Advisory Group of Experts on Immunization—report of the extraordinary meeting on the influenza A (H1N1) 2009 pandemic, 7 July 2009. Wkly. Epidemiol. Rec., 84, 301–304.
52. World Health Organization http://www.who.int/biologicals/areas/vaccines/thiomersal/en/
53. World Health Organization http://www.who.int/vaccine_safety/topics/thiomersal/Jun_2008/
54. Zahrani JA. Knowledge, attitude and practice of parents towards childhood vaccination. Majmaah J Health Sci. 2013;1(1):29-38
55. Zhu, F., Wang, H., Fang, H., et al. (2009): A novel influenza A (H1N1) vaccine in various age groups. N. Engl. J. MED., 361, 2414–2423.